ESSAYS ON MARKETS FOR TECHNOLOGY: THE ROLE OF LICENSING AS A COMPLEMENTARY STRATEGY TO INTERNAL R&D

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ESSAYS ON MARKETS FOR TECHNOLOGY: THE ROLE OF LICENSING AS A COMPLEMENTARY STRATEGY TO INTERNAL R&D

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To Krisztina, my parents and my brother

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SUMMARY

I study the role of licensed technologies in the R&D development process, the knowledge assimilation mechanism and the patent litigation procedure. I document that the use and adoption of licensed technologies is not a linear process and it has important strategic consequences. First, I focus on the joint effect of external and internal technologies and possible firm-level drivers of this relation. I find that, on average, internal R&D and licensing investments are neither complements nor substitutes. However, firms with higher levels of absorptive capacity, economies of scope, and past licensing experience are able to create positive synergies by combining the two types of investments. In addition, I find that the integration and the adoption of external technology may be limited by internal knowledge accumulation. Firms that experience an inward oriented knowledge accumulation process need to balance the trade-off between internal knowledge reliance and external knowledge assimilation. The negative relation between internal and external knowledge is positively mitigated by two organizational factors: absorptive capacity and the level of decentralization. Finally, assuming that companies are able to adopt external technologies, I find that licensed patents are more reliable than internal ones. In other words, external patents increase the probability of winning a patent lawsuit. Under this circumstance, firms are able to reduce patent uncertainty, limit market entry, and protect future revenue streams.

CHAPTER 1

INTRODUCTION

The conceptual framework of this dissertation lies at the intersection of strategy, innovation, markets for technology, and organizational theory research. The objective of this dissertation is to analyze two broad questions. First, are firms able to assimilate and integrate external knowledge with their existing knowledge and under what circumstances are firms more successful in this process? Second, how can firms exploit licensed technologies as a defensive strategy against market entry? In particular, I attempt to address these questions by looking at the firm-level of analysis and by trying to understand the role played by licensed patents under several circumstances: R&D development, knowledge assimilation and patent litigation. Addressing these questions requires an interdisciplinary approach; specifically, I draw insights from different streams of research including organizational theory, innovation research, the knowledge-based view of the firm, sociology, and economics. In this introduction, I briefly describe the three main chapters of my dissertation and highlight the main contributions.

I look at technologies developed outside of the firms' boundaries and I make an effort to identify the potential benefits and threats associated with their adoption. A large body of innovation research has examined the capabilities that firms possess in order to be innovative. Existing research has primarily focused on the role and antecedents of technologies that were produced internally and licensed out. However, firms exploit external technologies to boost their innovative performance; this in-licensing process depends on the ability to recombine, assimilate and transfer knowledge. Therefore, it is

important to understand how companies can benefit from their licensing strategy. To address this gap, I examine the impact of licensing investments on both sales and innovative performance when combined with internal knowledge. I document how licensed technologies can have a positive impact only under specific circumstances. In the three chapters of my dissertation, I examine the effect of acquired knowledge on firms' innovative output, sales performance, and patent litigation outcomes. The general setting of this dissertation is the pharmaceutical industry. I use multiple databases to follow a largely representative sample of incumbent firms. I primarily rely on licensing data as a measure of external technology acquisition and patent data to analyze drug litigations.

In the first chapter, I argue that a focus on the average relation between internal R&D and external technology may be misleading. I find that the level of complementarity and substitutability varies conditional on the existing capabilities of the firm. I attempt to provide a deeper understanding of the firm-level drivers of complementarity between these two types of investments through the structural estimation of a flexible innovation production function. Results suggest that on average internal R&D and in-licensing investments are neither complements nor substitutes, thus suggesting a complex relationship between the two forms of investments. In addition, I find that the degree of complementarity is enhanced for firms with stronger absorptive capacity, economies of scope, and past licensing experience. Overall, this chapter establishes the importance of firms' existing capabilities to create synergies between internal R&D and licensing acquisitions.

In the second chapter, I combine the markets for technology framework and research on organizational boundaries to examine the impact of internal knowledge accumulation and licensing acquisitions. I argue that when firms specialize in internal knowledge and adopt an inward oriented knowledge accumulation process, they can be reluctant to adopt external technologies. While recent studies have emphasized the importance of combining technologies from different sources, there is a lack of attention on the integration of external technologies into innovative production. This chapter focuses on the potential tension between external knowledge acquisition and internal knowledge accumulation. My results show that reliance on existing knowledge reduces the marginal effect of licensed technologies on firm market capitalization. As a consequence, this inward attitude may conflict with the exploitation of external technologies, thereby limiting the potential benefits associated with the markets for technology. I also find that higher level of absorptive capacity and a decentralized organizational structure moderate the negative bias towards external technologies. In essence, this chapter analyzes the relationship between internal knowledge and in-licensing investments, showcasing how companies can reduce the trade-off between internal knowledge accumulation and external technologies.

In the third chapter, I assume that firms are able to assimilate and adopt external patents and I examine how these technologies can be used as a defense mechanism to prevent market entry. Past research has considered when and why firms may choose to access the markets for technology. However, in the case of licensing little is known about the reliability of these external patents. "Weak" external patents can expose a firm to the loss of a protected revenue stream. In some industries, such as pharmaceuticals,

where development cycles are long, the loss of a revenue stream due to litigation can be a significant event. I focus on a unique legal action called a "Paragraph IV challenge" that is peculiar to the U.S. market: under specific circumstances, generic manufacturers may enter the market five years after drug commercialization and before patent expiration. This setting offers a natural experiment to test whether external technologies are more reliable than those developed internally. I find that acquired patents are more reliable than internal technologies, thus suggesting that the due diligence process effectively selects the best technologies. I also show that more profitable drugs have a higher probability of being challenged, further, the 2003 Medicare Modernization Act lowered litigation costs which, in turn, increases the likelihood of a challenge.

CHAPTER 2

BEHIND THE SCENES: SOURCES OF COMPLEMENTARITY IN R&D

2.1. Introduction

Markets for technology have been extensively studied (Arora and Gambardella, 1990, 1994a); however, there still remains little evidence about the determinants of technology demand in terms of the relationship between internal and external R&D (Arora and Gambardella, 1990). Firms choose their level of integration within the value chain, but the extent to which they adopt different R&D strategies as substitutes or complements remains uncertain. It is possible to identify three different scenarios: vertical disintegration, vertical integration and intermediate levels of integration.

Some firms, such as Morgan Stanley, have advocated a radical shift for the management of R&D in certain industries (Morgan Stanley, 2010; Shapiro, 2003). In particular, they argue that the pharmaceutical industry should abandon its current R&D model and fully adopt a "search and development" (S&D) model. Under an S&D framework firms would abandon all internal research and focus solely on development. Thus, 100% of a firm's drug candidates would come from external licensing and firms would adopt a vertical disintegrated structure. an opposite view is proposed by Pisano (2006), the author critizes a "market-based" organization sice it has not delived the promised innovation and reduction in R&D costs. Pharmaceutical firms should implement a more integrated structure to deal with R&D uncertainty and with the lack of results from the biotech sector. Under this view, firms should become knowledge integrators and exploit only few long-term collaborations that are very broad in scope.

For example, pharmaceutical companies should not sign 40 agrements per year but they should sign four or five agreements that focus on specific therapeutic areas or target families. While full adoption of an S&D model or a vertical integrated structure is an extreme position, some pharmaceutical companies have openly acknowledged a move toward intermediate level of integration based on more frequent engagement in external licensing. For example, in 2009, GlaxoSmithKline (GSK) terminated its legendary neuroscience program in order to free up capital to meet its stated goal of allocating 50% of its R&D budget to external projects (Knowles and Higgins, 2011).

The S&D model implicitly suggests that internal and external R&D are substitute activities in the sense that implementation of one activity reduces marginal return on the other activity. Complementarity would arise if an increase in one of these activities increased the marginal returns from the other activity (Gans and Stern, 2003). Substitution between these activities is consistent with the extreme case of backward integration, whereby firms rely exclusively on internal R&D investments. Backward integration dominated the organization of R&D in the past century. Substitution is also consistent with the opposite case, whereby a non-integrated firm relies exclusively on external technology, perhaps yet to be developed, as in the case of the S&D model. Ultimately, the decision to choose between these two types of R&D is influenced by whether synergies exist between them. For example, internal R&D and licensing could fulfill quite distinct yet complementary purposes. R&D can serve functions not directly tied to the creation of new products, such as concept exploration, hypothesis testing, and market credibility, which are all activities that can complement the investment made on a technology licensed from other firms or institutions.

Our review of the literature suggests that empirical evidence does not conclusively support substitution or complementarity across all industry settings. Moreover, there is surprisingly little research on the contextual factors that determine whether these two activities are complements or substitutes. Accordingly, the major objective of this paper is to provide a deeper understanding of the firm-level drivers that determine the degree of complementarity between internal and external R&D. To accomplish our goal, we adopt a two-step empirical strategy. In the first step, we estimate the coefficients of a flexible CES-Translog innovation production function (Pollak *et al.*, 1984) to find the most appropriate functional form to use in our context. We then provide structural estimates of the degree of complementarity or substitutability between these two types of R&D investments that vary across firms and time.

Our study is focused on the global pharmaceutical industry, which is an ideal research setting for several reasons. In the pharmaceutical industry, internal productivity failures and the lack of capabilities in emerging technology, coupled with an increase in new external opportunities, have influenced the balance between internal R&D and in-licensing strategies (Malerba and Orsenigo, 2000). Furthermore, internal and external R&D are considered major drivers of firm performance (Scherer, 2007). Finally, the detailed availability of longitudinal measures relating to both internal and external research activities and their product innovation output allows us to directly analyze the marginal productivity of these investments and drivers.

Our results suggest that, on average, internal R&D and in-licensing investments are neither complements nor substitutes in the global pharmaceutical industry. However, we show that the degree of complementarity is enhanced for firms with stronger

absorptive capacity, economies of scope, and past licensing experience. Taken together, our results highlight the complexity of this relation and suggest that a simple categorization (complement or substitute) may be misleading. In such a context, the framework presented in this paper appears to be valuable, since it recognizes the importance of heterogeneity across firms in terms of affecting complementarity of internal and external R&D capabilities within narrowly defined industries. Conditional on data availability, such an approach could be readily applied by other researchers to examine similar issues within various industry contexts.

2.2. Literature review

2.2.1. Complements or substitutes?

Firms must continuously invest in the development of new products in order to stay competitive. Sources of innovative knowledge are no longer limited to internal investments, but they include more significant contributions from external sources, such as licensing. The importance of technology licensing has long been recognized in the literature on industrial organization. However, past research on markets for technology has mostly focused on the supply-side drivers of licensing decisions (Arora and Ceccagnoli, 2006; Arora and Fosfuri, 2003; Arora *et al.*, 2001; Katz and Shapiro, 1987). Less attention has been paid to the incentive to buy technology in the market, particularly on the relationship between internal and external R&D (Arora and Gambardella, 2010). This is an important gap in the literature, because technology buyers in most high-tech industries conduct extensive internal R&D, which could alter their external investment strategy. If it does, this creates a potential tension between developing technology

internally and obtaining it externally. This tension raises the question of whether internal and external R&D investments are complements or substitutes. While a few studies have recently attempted to address this question, results to date are not conclusive.

Several empirical studies support the substitution viewpoint. Pisano's (1990) findings suggest that substitution is driven by transaction costs and their influence on the decision to externally expand R&D. Laursen and Salter (2006) find that internal R&D investments negatively moderate the relationship between external knowledge (licensing) and innovation performance. In a study on investments in advanced Internet technologies, Forman *et al.* (2008) find a substitute relationship between internal firm resources (e.g., programmers) and external technologies. In a model of technology adoption, they find that the marginal contribution of internal firm resources tends to diminish within large urban areas. It is therefore possible that the external resources available in cities are partial substitutes for both establishment-level and firm-level internal resources.

Complementarity between internal and external R&D, on the other hand, implies that these two forms of R&D coexist and are interdependent. Unlike the substitute relationship, complementarity implies that firms acquiring external technologies must also continue to engage in internal R&D. Several studies provide evidence in support of complementarity (Cassiman and Veugelers, 2006; Lowe and Taylor, 1998; Png, 2012; Tsai and Wang, 2008). Cassiman and Veugelers (2006), for example, provide empirical evidence in support of complementarity between internal R&D and external technology acquisition strategies (these include licensing, alliances, and acquisitions). The study of Tsai and Wang (2008) on Taiwanese electronics manufacturing demonstrates that external technology acquisition does not contribute to firm performance *per se*, but does

show that external acquisition of technology has a positive effect on performance when interacting with internal R&D.

Other empirical evidence, consistent with complementarity, suggests that external know-how can quickly bring new resources to a firm during different stages of production. New knowledge, such as externally generated patents or partially developed compounds, can boost the development process and potentially increase expected revenues. Along these lines, Higgins and Rodriguez (2006) find that internal knowledge is combined with technology acquisition to fill research pipeline gaps. Danzon *et al.* (2007) argue that firms acquire technology in order to replenish pipeline gaps and respond to excess capacity generated by patent expirations. Similarly, Chan *et al.* (2007) find that firms engage in the external technology market as a result of downstream cospecialized complementary assets.

In contrast, Vega-Jurado *et al.* (2009) find no evidence of complementarity nor substitution in the Spanish manufacturing sector. These authors analyze the effect of external knowledge sourcing strategies on the development of both product and process innovation for a sample of innovative Spanish firms. Their results suggest that firms rely on both internal R&D and external knowledge sources, but that the two activities do not have synergistic effects.

In sum, previous research demonstrates the importance of effective internal R&D and external technology acquisition strategies for superior economic performance. However, there is mixed evidence and limited understanding concerning the relationship between these two types of activities, especially their conditioning drivers. Moreover, the scope of prior work has often been limited by data availability, as cross-sectional survey

data allows—at best—only analysis of discrete choices of technology that a firm could "make" or "buy" at a specific point in time.

2.2.2. Drivers of complementarity

Our literature review suggests that the firm-level drivers of the degree of complementarity or substitutability between internal R&D and in-licensing can be grouped into factors determining a firm's absorptive capacity, economies of scope, and licensing experience.

2.2.2.1. Absorptive Capacity

Absorptive capacity reflects a firm's ability to identify, assimilate, and exploit knowledge from the environment (Cohen and Levinthal, 1990). Arora and Gambardella (1994b) formally link this concept to a firm's external technology acquisition strategy. They emphasize two components of absorptive capacity that are relevant to the acquisition of external technology through alliances. One component is the ability to evaluate external technology, which depends on a firm's upstream research capability. Another component is a firm's ability to utilize external technologies, which depends on its technological and development skills.

We build on Arora and Gambardella's contribution by suggesting that both types of firm capabilities tend to be associated with a stronger complementarity between internal and external R&D activities. On one hand, an increase in the cumulated investment in internal R&D, especially when the type of R&D is more basic in nature, tends to generate scientific capabilities, which in turn makes in-licensing more efficient,

as it enhances the selection of external technology projects. On the other hand, higher levels of internal R&D, especially when R&D is more geared toward design or development of new products increases the returns from external technology investments by facilitating the effective integration of external technology within the buyer's value chain. We will exploit this distinction between the ability to evaluate and utilize external technology in our empirical setting in order to guide our empirical measurement and analysis.

2.2.2.2. Economies of scope

A second set of drivers of complementarity between internal R&D and in-licensing relate to the concept of economies of scope, defined as the cost savings that are generated from adopting different activities in multiple markets (Fosfuri and Rønde, 2009; Henderson and Cockburn, 1996). The advantage gained through exploitation of economies of scope arises from sharing or jointly utilizing production inputs such as technological resources. When technologies are licensed for use in one market, they can freely or at reduced additional cost be re-adopted to other markets or products. Therefore, the opportunity to share technologies across different projects facilitate the generation of synergies among them by creating links between resources that would otherwise remain separate. While the logic of economies of scope typically refers to the benefits of related diversification in terms of cost advantages, these benefits can also be formulated in terms of products and services. The external knowledge developed for a given technological area may potentially be beneficial to the development of products in other technological areas. Given that knowledge can be articulated and codified within the firm (Zollo and

Winter, 2002), the external knowledge acquired for a specific project can be utilized to improve the current development of products in other technological areas.

Following this logic, we expect that firms with broader experience across different technological areas to be characterized by a stronger degree of complementarity between internal R&D and in-licensing. This implies that such firms may be using knowledge developed in different fields additively in the innovative process (Henderson and Cockburn, 1996). Complementarities may arise if technologies purchased from external sources have different technical specifications, and thus are useful to fulfill internal capability gaps. In such cases, economies of scope should increase the synergetic combination of internal and external inputs.

2.2.2.3. Licensing Experience

The logic underlying the effect of prior licensing experience on the complementarity between internal and external R&D is similar, in many respects, to the concept of absorptive capacity examined above. Licensing experience refers to the cumulative experience in leveraging external knowledge, whereas absorptive capacity is based on the cumulative experience developed by investing in internal knowledge. Under this view, collaborative agreements, such as licensing, joint ventures, and acquisitions, may enhance a firm's ability to more effectively combine internal and external technologies.

The literature suggests that firms with prior licensing experience are more likely to have developed effective communication mechanisms, more flexible organizational structures, and other successful organizational routines that can facilitate the integration

of external technologies within existing R&D structures (Hoang and Rothaermel, 2010; Zollo and Winter, 2002). Indeed, firms vary in the extent to which their organizational structure supports the management of technology acquisition. For example, Pfizer has recently invested in creating a new division called "the Research Network Initiative," in order to allow external technologies from their various partnerships to become more accessible to internal projects.[1]

Furthermore, similar to the effect of scientific capabilities highlighted in the previous section, firms with more extensive licensing experience are better able to identify valuable external technologies that best fit their internal R&D efforts, thus increasing the synergies between the two activities.

2.3. Model description and estimation procedure

2.3.1. Step 1: CES-Translog specification and functional form tests

We assume that each firm is characterized by an innovation production function (n), which depends on investments for the acquisition of external technology (R_e), internal R&D expenditure (R_i), and a constant term that represents firm-specific effects as well as other exogenous components affecting the productivity of resources invested in innovation (S):

$$n = f(R_i, R_e, S) \quad (1)$$

[1] http://www.labnews.co.uk/comment/big-ask/dating-agency-scientists-andrew-mcelroy/. (last accessed: 06/06/2012)

Hereafter, the firm and time subscripts are omitted for simplicity. We start by adopting a CES-Translog specification, a flexible, functional form that nests the Cobb-Douglas, CES, and Translog specifications. Previous work using a CES-Translog specification include Pollak *et al.* (1984) and Dewan and Min (1997). The former provide estimates of a CES-Translog cost function and find that it fits significantly better multiple datasets covering different industries and countries than had been previously used in the literature. The latter builds upon Pollak *et al.* (1984) to directly estimate the CES-Translog as a production function to analyze the effect of IT and non-IT capital on productivity in the IT industry.

There are two main advantages of using a CES-Translog specification. First, it is a flexible, functional form that is compatible with a wider range of substitution possibilities than CES or Translog. Second, we can exploit its nested properties to find the best functional form that describes the innovative process without losing efficiency in terms of likelihood (Pollak *et al.*, 1984) and without imposing *a priori* restrictions on our model. Overall, this methodology helps improve upon existing research, because estimating the complementarity relationship between internal and external R&D using restrictive production models may cause specification errors and yield biased econometric estimates.

We define our CES-Translog production function as:

$$(2)\ \log n = \quad S + \frac{1}{\rho}\log\left(\alpha_i R_i^{-\rho} + \alpha_e R_e^{-\rho}\right) + \beta_i(\log\ R_i)^2 + \beta_e(\log\ R_e)^2 + \gamma_{\text{ie}} \log\ R_i \log\ R_e + u,$$

where R_i and R_e represent internal R&D expenditure and in-licensing investment (external R&D), $\alpha_i + \alpha_e = 1$, and u is a random error term representing the unobserved drivers of the internal and external R&D investments. Equation (2) shows that it is possible to innovate even if a firm does not invest in these two types of R&D, due to the effect of an exogenous component, *S*, which might include factors such as knowledge flows from other firms or universities. The additive linear term is equivalent to a classic CES specification, where ρ represents the elasticity of substitution between R_i and R_e. The βs and γ coefficients represent, respectively, the quadratic impact and the cross-effect of R&D investments on the production of innovations.[2]

According to Pollak *et al.* (1984), researchers can exploit the nested properties of the CES-Translog to test for other functional forms, and to reduce model complexity without reducing its estimation efficiency. These tests offer more flexibility to researches in modeling innovation functions, because they do not require that prior assumptions on data behavior be made. The Cobb-Douglas, CES, and Translog forms are all special cases of the CES-Translog. When all quadratic terms are equal to zero, we obtain a CES function. The Cobb-Douglas is obtained when all quadratic terms are equal to zero and ρ tends to zero. The Translog specification can be found when ρ approaches 0 and all the other parameters are different from zero. These nested properties enable testing for model specification using conventional test procedures (Pollak *et al.*, 1984). Table 2.1 summarizes these three specification tests. A rejection of all the specification tests presented in Table 2.1 would lead to the adoption of the CES-Translog innovation

[2] Our definition of the degree of complementarity/substitutability is based on the cross partial derivative of the production function. This is different from the elasticity of substitution, which is defined as the percentage change in factor proportions due to a change in the marginal rate of technical substitution (Hicks, 1932)

production function. However, a simpler, but still efficient functional form can be adopted if one of the tests is rejected.

Table 2.1. Functional form tests

Functional form	**Coefficients test**
Cobb-Douglas	$\rho = 0$; $\beta_i = 0$; $\beta_e = 0$; $\gamma_{ie} = 0$
CES	$\beta_i = 0$; $\beta_e = 0$; $\gamma_{ie} = 0$
Translog	$\rho = 0$

Coefficients from the CES-Translog production function (Equation 2).

2.3.2. Step 2: Estimation of the degree of complementarity

After testing the coefficients of the CES-Translog, we are able to choose the most efficient functional form specification to be used in our model. Our empirical findings, discussed below in Section 2.5.1, will show that the Translog production function better fits our data. Therefore, we will only compute and focus on the degree of complementarity or substitutability for the Translog production function in the sections that follow. The Translog specification is defined as follows:

$$(3)\ n = R_i^{\alpha_i} R_e^{\alpha_e} e^{S+\beta_i(\log R_i)^2+\beta_e(\log R_e)^2+\gamma_{ie}\log R_i \log R_e+u},$$

where *S* is the exogenous component of the production function, *u* is the error component, and R_i and R_e represent internal and external research, respectively. We estimate the Translog by taking logarithms of both sides of (3), which allow us to employ linear estimation techniques.

The marginal productivity of internal and external R&D using the Translog specification can be written as follows:

$$(4)\ \frac{\mathrm{dn}}{\mathrm{dR_i}} = \frac{n}{R_i}\left(\alpha_{\mathrm{i}} + 2\,\beta_{\mathrm{i}} \log R_i + \gamma_{\mathrm{ie}} \log R_e\right) = \frac{n}{R_i}\mathrm{Z_i}$$

$$(5)\ \frac{\mathrm{dn}}{\mathrm{dR_e}} = \frac{n}{R_e}\left(\alpha_{e} + 2\,\beta_{e} \log R_e + \gamma_{\mathrm{ie}} \log R_i\right) = \frac{n}{R_e}\mathrm{Z_e}$$

We then estimate the degree of complementarity or substitutability using the following cross-partial derivative:

$$(6)\ \frac{d^2n}{dR_i dR_e} = \left[\frac{n}{R_e}\left(\alpha_{\mathrm{e}} + 2\,\beta_{\mathrm{e}} \log R_e + \gamma_{\mathrm{ie}} \log R_i\right)\frac{\mathrm{Z_i}}{R_i} + \frac{\mathrm{n}\,\gamma_{\mathrm{ie}}}{\mathrm{R_i R_e}}\right] =$$

$$\frac{\mathrm{n}}{\mathrm{R_i R_e}}\left(\mathrm{Z_i Z_e} + \gamma_{\mathrm{ie}}\right) = \frac{\mathrm{n}}{\mathrm{R_i R_e}}\tilde{\mathrm{Z}},$$

where $\tilde{Z} = \left(\mathrm{Z_i Z_e} + \gamma_{\mathrm{ie}}\right)$ and all other variables are as defined above. In contrast to the signs for CES and Cobb-Douglas, the sign of $\frac{d^2n}{dR_i dR_e}$ for the Translog functional form is less intuitive. Although the values of R_i, R_e, and *n* are positive, the sign of $\tilde{Z}$ is ambiguous and we cannot predict *ex-ante* whether internal and external R&D investments are complementary or substitutable. However, we can estimate the predicted

value of n and $\tilde{Z}$ for each firm year by estimating the log-log specification of the innovation production function expressed by Equation (3). We then evaluate $\frac{d^2n}{dR_i dR_e}$ for representative (mean or median) values of R_i, R_e, and the exogenous predictors of n, with particular attention to the firm-level drivers of complementarity summarized in Section 2.2.2.

2.3.3. Empirical strategy

Our estimation procedure involves two steps. First, we identify whether the innovation production function is better represented by a Cobb-Douglas, CES, Translog, or CES-Translog by estimating and testing the coefficients of Equation (2). Second, we select the best functional form to estimate the degree of complementarity/substitutability. We are able to estimate all model parameters regardless of the functional form of the production function. Therefore, all the equations are identified. Once the innovation production function is estimated, we can compute the sign and magnitude of the cross-partial derivative $\frac{d^2n}{dR_i dR_e}$. Notice that $\gamma_{\text{ie}} \equiv \frac{d^2 \log n}{d \log R_i d \log R_e}$ in (3)-(6) represents a percentage change in the elasticity of internal R&D for a percentage change in licensing or vice versa. While this is a more easily interpretable notion of complementarity, an evaluation of the sign of the cross-partial derivative (6) suggests that its sign is not determined by the sign of γ_{ie}.

The production functions presented in the previous sections can be used in the context of a profit maximization model with endogenous internal and external R&D investment levels (available from the authors upon request). Such models generate

exclusion restrictions which imply that variables affecting the optimal level of internal R&D and licensing (external R&D) do not affect the innovation production function other than through R_i and R_e. This provides information about instrumental variables that can be utilized in order to deal with the endogeneity of internal R&D and licensing. The source of endogeneity comes from unobserved factors that may drive both the production of innovations as well as the efficiency of internal and external R&D investments. As discussed more fully below, we use exogenous drivers of the expected value of an innovation as instruments for internal and external R&D investments in the innovation production function. We also experiment using controls for unobserved firm-specific heterogeneity to test the sensitivity of the results to our identification strategy.

2.4. Data

Our sample is based on a unique longitudinal dataset built from a variety of sources. We began by creating a comprehensive list of global pharmaceutical firms from Pharmaprojects that were active in drug development at any point during 1997–2005. Data includes both the timeline of drug development (*e.g.*, the various stages of clinical trials, FDA approval, and project discontinuations) and detailed information on the potential size of the market and the novelty of the compound.

Next, we matched our list of firms with Compustat, collecting data on firm sales, total R&D expenditures, and the number of firm employees. Licensing information was obtained from Deloitte ReCap and includes data on royalties, up-front payments, and milestones. Finally, from IMS MIDAS™ we obtained product-level promotion expenditures. All financial variables are in year 2000 constant US dollars. Descriptive

statistics are provided in Table 2.2 and correlations are presented in Table 2.3 (both provided in Chapter 2 Appendix).

Our final sample consists of 94 global pharmaceutical firms active in drug development between 1997 and 2005. Of those, 85% of the firms were located in North America and 12% were located in Europe and the U.K. The average firm has approximately 11 compounds in its pipeline. Our firms, like most major pharmaceutical companies, operate in a number of therapeutic areas. In the sample, the average number of therapeutic categories per firms is six. Almost one-third of the compounds under development are focused in three therapeutic areas: central nervous system, alimentary tract and metabolism, and cardiovascular.[3]

2.4.1. Dependent variables

Product pipeline. Our dependent variable is the firm-year product pipeline, which represents a firm's innovative output. The importance of studying a firm pipeline is based on the idea that compounds are developed in stages, all of which require different resources and capabilities in order to reach commercialization. These resources can be developed internally or acquired through the markets for technology. Using data from Pharmaprojects, we generate a yearly pipeline stock by cumulating the number of FDA approved drugs and those being developed for each firm in our sample.[4] To account

[3] ATC stands for Anatomical Therapeutic Chemical as defined by the World Health Organization (http://www.whocc.no/). These therapeutic classes are: A: alimentary tract and metabolism; B, blood and blood forming organs; C, cardiovascular system; D, dermatologicals; G, genitourinary system and sex hormones; H, systemic hormonal preparations, excl. sex hormones and insulins; J, anti-infectives for systemic use; L, antineoplastic and immunomodulating agents; M, musculoskeletal system; N, nervous system; P, antiparasitic products, insecticides, and repellents; and R, respiratory system.

[4] To deal with observations equal to zero (10% of our sample), we compute our pipeline variable as log(1+x). We also tried Poisson's estimation for count data models. Our results remain robust.

for development uncertainty, compounds are weighted by average probabilities of successfully reaching FDA approval, conditional on their phase of development (Grabowski, 2002). In this way, we provide greater weight to later-stage drug candidates (Higgins and Rodriguez, 2006). This is consistent with our objective to compare the efficiency of internal R&D and in-licensing in obtaining new, marketable products.

2.4.2. Independent variables

Internal R&D investments. We compute internal R&D investments using data from Compustat and Deloitte ReCap. R&D data from Compustat includes expenditures in R&D that could be performed internally or externally.[5] In order to isolate internal R&D, we use licensing data from Deloitte Recap and subtract it from the Compustat data. The resulting difference is our proxy for purely internal R&D expenditures. Finally, since developed knowledge can become obsolete over time, we use a 15% depreciation rate to compute an internal R&D stock variable (Hall, 1993).

In-licensing investment (external R&D). We use Deloitte ReCap data to collect licensing payments. Our in-licensing variable is based on the sum of milestones and

[5] In-licensing upfront fees and milestones are expensed when incurred as R&D expenditures (FAS 2R.12). The following examples from public filings explain the underlying accounting principles. 1) ABBOTT 2010 10-K SEC filing (p. 51) states:

> "Internal research and development costs are expensed as incurred. Clinical trial costs incurred by third parties are expensed as the contracted work is performed. Where contingent milestone payments are due to third parties under research and development arrangements, the milestone payment obligations are expensed when the milestone results are achieved."

2) BIOMARIN 2010 10-K SEC filings (p. 43) states:

> "Research and development expenses include expenses associated with contract research and development provided by third parties.... Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables."

3) MERCK 2010 10-K SEC filings (p. 115) states:

> "Research and development is expensed as incurred. Upfront and milestone payments due to third parties in connection with research and development collaborations prior to regulatory approval are expensed as incurred."

upfront payments.[6] As with the internal R&D variable, we build the stock of licensing investment using a 15% depreciation rate (Hall, 1993). In the case of missing values, we imputed the payments based on the average investment for agreements with similar characteristics, such as the same year of signing, stage at signing, disease, and type of technology.[7] Because the stock of licensing expenditures also capture a firm's licensing experience, we will also use this variable to evaluate the extent to which such experience may affect the degree of complementarity between the internal generation and external acquisition of technologies.

2.4.3. Instrumental variables for internal and external R&D

As noted above, internal R&D (R_i) and in-licensing (R_e) are correlated with unobserved productivity factors affecting both inputs and output of innovation. Our R&D optimization model suggests that variables affecting the expected value of an innovation should only affect the production of innovation through these variables' effects on the levels of internal and external R&D investments.[8] We therefore use variables that should affect the profitability of marketed drugs, such as potential size of the market, drug novelty, number of competitors, and the strength of a firm's complementary assets. As shown in the empirical results section, the above instruments appear to have sufficient

[6] We are not able to include royalties in our in-licensing measure because they are included in the income statement as part of operating expenses or as cost of sales and are not explicitly available in a consistent way in either public documents or Deloitte ReCap. Given this limitation, we acknowledge that our in-licensing measure is downward biased and most likely provides a lower bound of the in-licensing effect on innovative output.

[7] Only 9% of data had missing values for this variable. To check the robustness of our results to the imputation method, we re-estimated the model without the imputed values, and the results were unchanged.

[8] The formal optimization model is available from the authors upon request.

power and seem to be uncorrelated with the econometric error term, as indicated by the tests for instrument validity.

First, we use potential product market size as an instrument for internal and external R&D investments, because it reflects exogenous drivers of the future demand of the firm. In the case of successful approval and commercialization, each firm is able to service the potential market and gain the associated revenues. The larger the expected size of the market, the higher will be the overall R&D effort (both internal and external investments) to develop a final product (Acemoglu and Linn, 2004). Pharmaprojects includes estimates of the potential product market size for drugs in development. We compute the expected market size for pipeline products by summing the estimated values of each firm's drugs in each year.

Second, we use drug novelty as another potential instrument. This data is made available by Pharmaprojects, which contains independent ratings about the novelty of compounds. Each compound's novelty is categorized using a discrete range between 1 and 6, where the value 6 represents the most innovative drugs. Consistent with recent work, our measure of drug novelty is based on drugs with the highest novelty rank, corresponding to "leading compounds" (Ceccagnoli and Jiang, 2012; Jaffe *et al.*, 1993; Perelman, 2003). We then use the proportion of novel drugs in the pipeline for each firm-year of each firm as an additional instrumental variable.

Third, we use the number of competitors to proxy for the incentive to be innovative and productive. While the effect on incentives for product innovation is ex-ante ambiguous, the number of competitors does affect market prices and demand elasticity (Mazzoleni and Nelson, 1998). This variable reflects the number of firms with

at least one product sold in the main therapeutic area (ATC) of the focal company. The data was collected from IMS MIDAS™.

Finally, ownership and strength of downstream complementary assets is an important driver of the appropriability of returns from innovation (Teece, 1986). We use two variables to proxy for a firm's strength of complementary assets. First, we employ a firm's detailing expenditures, obtained from IMS MIDAS™, to capture that firm's marketing capability. Detailing is defined as promotion activities directed toward physicians and hospitals, journal advertising, and direct-mail. We also use the stock of a firm's trademarks to proxy for that firm's brand capital (Fosfuri *et al.*, 2008). These two instruments are associated with both internal and external R&D investments, since they enhance the appropriability of both types of investments. We collect data on active trademarks from the USPTO and use them to build a stock variable.

2.4.4. Complementarity drivers and other control variables

One theoretical argument related to absorptive capacity suggests that the firm's cumulated investment in basic research is complementary to in-licensing. Data pertaining to analysis of this argument is typically unavailable using secondary sources. From an empirical point of view, a way around this problem is to identify the type of R&D conducted by each firm. Indeed, the complementarity between commonly observed measures of R&D expenditures (which includes applied research and development activities) should increase the more a firm conducts relatively basic research activities. Consistent with this idea, Cassiman and Veugelers (2006) suggest that the extent to which a firm relies on more "basic" know-how affects the strength of the

complementarity between internal and external innovation strategies. Therefore, as measures of a firm's type of R&D we use the focal firm's cumulative number of scientific publications, according to data provided by the Web of Science. A strong scientific publications record indicates that a firm's technology is based on advances in science. As a measure of absorptive capacity, which reflects a firm's ability to effectively integrate external technology, we follow Arora and Gambardella (1994b) and utilize two alternative measures: the cumulative number of patents granted each year to the focal firm (available from the USPTO) and the cumulative stock of internal R&D.

To measure the potential for economies of scope across different scientific fields, we use the total number of therapeutic areas covered by the drugs in the pipeline of the focal firm each year, which we label, "number of ATCs". Firms that operate in different ATCs may develop capabilities unique to a specific therapeutic area and exploit possible economies of scope. Moreover, innovations in the pipeline can often be used in multiple therapeutic areas, thereby increasing their application possibilities. For example, Topamax® was originally approved as an anti-epileptic but was subsequently used for obesity and peripheral pain.

Among other exogenous variables, we include firm size, which is measured by the total number of firm employees (obtained from Compustat) and intended to control for size-related factors that might drive differences in innovative performance. To control for possible differences in uncertainty between in-licensed and internally developed drugs, we include the percentage of licensed compounds (gathered from Pharmaprojects) that a firm has at each phase of the clinical development process. Indeed, firms that license new compounds may face a higher probability of success because they pay for a compound

that has already gone through part of the earliest and more uncertain stages of the development process.[9]

Finally, we control for industry, firm, location, and year of unobserved fixed effects. To control for technological opportunities and other unobserved factors associated with the main technological field of the focal firm, we identify the primary ATC as the therapeutic are with the highest level of annual sales, then we include a set of dummy variables that would equal one for the main therapeutic area of the focal firm (based on the primary ATC) and zero otherwise. Given our definition of primary ATC, the ATC dummy variables vary over time. We also include specifications with year dummies and controls for firm fixed effects. The latter are included to control for firm heterogeneity. In models without firm-fixed effects, we also include 4-digit SIC-code dummies and geographic location dummies (North America, Europe, and other).

2.5. Results

2.5.1. First step: Functional form tests

Our estimation procedure starts by estimating the coefficients of a CES-Translog production function (Equation 2). The tests are summarized in Table 2.1. The advantage of adopting a flexible specification in the first step is due to its nested properties. Equation (2) allows us to test whether the production function can be simplified by using a Cobb-Douglas, CES, or Translog function. Our regression specification tests are

[9] Pisano (1997) finds evidence of the existence of a market for lemons in the external technology market. If true, this would suggest that firms would not achieve any reductions in risk and the expectations for success of those products would be less than internally developed molecules. However, Arora *et al.* (2009)find the opposite to be true. They find that compounds licensed during preclinical trials are as likely to succeed as internal compounds of the licensor. Danzon *et al.* (2005) also find that products developed in an alliance tend to have a higher probability of success.

reported in Table 2.4. In this first set of analyses, we are not interested in the marginal effect of our independent variables but rather focus only on the specification tests described in Table 2.1. Marginal effects and the degree of complementarity or substitutability, if any, are the focus of the second step of our empirical estimation procedure, discussed below.

We report the results for different models in Table 2.4. Model (1) is estimated using OLS Fixed Effect. It includes our main variables (internal R&D and licensing expenditures) and our full set of controls, including firm fixed-effects. Model (2) is estimated using GMM and incorporates the main variables and a full set of controls.[10,11] The instrumental variables pass the validity tests, as discussed in Table 2.4.

Our results, which are robust across the estimated models, indicate that ρ is not significantly different from zero. As a result, we can adopt a Translog specification for our production function, as defined by Equation (4). Moreover, we clearly reject the possible use of both a Cobb-Douglas and CES specification, because the related tests specified in Table 2.1 are significant. While ρ is not significantly different from zero, all the coefficients on the quadratic terms (β_i, β_e, and γ_{ie}, respectively) are jointly different from zero.

[10] The nonlinearity of Equation 4 does not allow us to eliminate the firm fixed effects using first-differences, nor by transforming the data to within-firm deviations. As a result, we control for unobserved firm heterogeneity using a set of firm-specific dummy variables.

[11] The GMM model with all controls (2) and all firm fixed-effects, however, did not converge. Thus, it is not reported. Details are available from the authors upon request.

Table 2.4. Specification Test Results Using CES-Translog production function

		Model (1) NONLINEAR OLS	**Model (2)** GMM
Tests	Cobb – Douglas	1480.7***	428.36***
	CES	1478.1***	339.51***
	Translog	0.45	0.18
	Firm Fixed effects	Yes	No
	Number of Observations	748	632
	Over-identification test (p-value)		0.767

- The table reports Chi-Square statistics, with *** denoting p-value < 0.01, related to the Wald test of hypotheses presented in Table 2.1.
- Both models include the main variables (*R&D* and *Licensing*) and the full set of controls. Model (1) also includes a full set of firm-specific dummy variables. Model (2) estimated with firm fixed-effects did not converge.
- We use *Promotion*, *Trademarks*, their squares, cross product, logs of square terms, and cross-product of logs as instruments for internal and external R&D and the related non-linear terms. Auxiliary first-stage regressions (OLS linear regressions "within" firm) suggest that the instruments have power. Indeed, the F-test of the joint effect of the instruments on each endogenous variable are 57.97, 5.38, 73.03, 12.57, 7.34 for R&D, the log of R&D-squared, licensing, the log of licensing-squared, and the cross-product of the logs of R&D and licensing, respectively.

2.5.2. Second step: Estimating the degree of complementarity/substitutability using the Translog production function.

After identifying Equation (4) as the appropriate innovation production function, we focus on estimating the degree of complementarity and its distribution across key firm characteristics. To facilitate estimation and interpretation of the coefficients, we adopt a log-log form of the Translog. This transformation makes the model linear with respect to the natural logarithm of our main independent variables. We then estimate the elasticities

and the degree of complementarity by taking the derivative with respect to the logarithm of internal R&D and in-licensing (external R&D).

The estimates of the Translog are reported in Table 2.5. We use three different estimation methods: a benchmark panel data fixed-effects model with instrumental variables estimated with GMM (columns 1-4), a panel random effects model (column 5), and a panel fixed effects model (column 6). The magnitude and significance of the cross-partial derivative $\frac{d^2n}{dR_i dR_e}$ (Equation 6) associated with the models of Table 2.5 (in Chapter 2 Appendix) are reported in Table 2.6. The cross-partials are evaluated at the mean and median of the variables included in Equation (6).

Table 2.6. Degree of complementarity/substitution.

	Panel GMM Fixed Effect				**Panel RE**	**Panel FE**
	(1)	(2)	(3)	(4)	(5)	(6)
Mean	-0.021	-0.031	-0.029	-0.019	-0.0001	0.001
Standard Error	0.033	0.033	0.024	0.017	0.001	0.001
Median	-0.02	-0.034	-0.032	-0.012	-0.0001	0.0008
Standard Error	0.033	0.041	0.031	0.011	0.001	0.0007

The table presents estimates of the cross-partial derivative $\frac{d^2n}{dR_i dR_e}$ (Equation 6) at the mean of the sample.

Overall, these results suggest that internal R&D and in-licensing expenditures are neither complements nor substitutes. In particular, the estimated cross-partials presented in Table 2.6 are not significantly different from zero across estimation methods.

One possible explanation may reside on the specificity of the drug discovery process. Pharmaceutical firms rely on external technologies in all development stages, and licensed drugs may be used to either substitute an existing stream of research or to complement it. In-licensing is one way to access new knowledge, and new knowledge boosts innovation. However, in-licensing may have two opposite mechanisms. On one hand, external knowledge can fill gaps in internal capabilities. On the other hand, external knowledge can complement internal knowledge by integrating the two sources of knowledge.

These results may not be significant because the complementarity effect experienced by some firms may be offset by the negative effect experienced by others. It follows that studying complementarity without understanding its drivers and the distribution across firms' characteristics may generate misleading results.

The results presented in Table 2.6 improve upon the existing literature in several ways. Our use of in-licensing investments provides more direct evidence on the marginal productivity of the financial resources invested in innovation. The extant literature more commonly uses a stock of external deals as a measure of external R&D or self-reported discrete measures of whether a firm acquires technology in the market. Furthermore, our empirical approach offers a new method to estimate complementarity without imposing methodological restrictions on the estimation, which could bias the results. Finally, and

more substantively, our results indicate that internal R&D and in-licensing do not, on average, have a significant joint effect on the production of new drugs.

2.5.3. Firm-level drivers of complementarity

To identify the impact of potential drivers of complementarity, we first present a graphical analysis of the cross partial derivative $\frac{d^2n}{dR_i dR_e}$ (Equation 6) obtained using our benchmark GMM instrumental variable method with fixed effects. The objective of this analysis is to understand whether firms that perform better than others across the four different drivers experience a different level of complementarity among the two types of investments. Figure 2.1 (in Chapter 2 Appendix) reports the values of the degree of complementarity captured by the cross-partial over the range of our measures of absorptive capacity (scientific publications, stock of internal R&D, patents), economies of scope (number of therapeutic categories, or ATC), and licensing experience (stock of in-licensing investments).

In all of the five graphs, the sign and magnitude of the joint effect vary with changes in the levels of the drivers. Overall, $\frac{d^2n}{dR_i dR_e}$ exhibits a positive trend in all cases, thus confirming that a higher level of complementarity is associated with higher levels of drivers. These findings confirm the complexity of the relationship between internal and external R&D investments; they also suggest that most previous studies on complementarity have not been able to ascertain whether a more composite relationship exists than can be revealed by the estimated average effect. A clear conclusion on

whether two activities are either complementary or substitute may be non-informative, since the joint effect changes across different ranges of value of key firm characteristics.

As a robustness measure, we present estimates in Table 2.7 (in Chapter 2 Appendix) of the Translog production function (Equation 4) using our benchmark GMM method with firm-fixed effects within sub-samples of firms characterized by either low (bottom 25%) or high (top 25%) levels of the distribution of the examined driver.

For an analysis of the significance of the differences across groups, we present tests for mean complementarity differences across groups of firms defined using bottom and top quartiles of the distributions of the examined drivers for both full and split-sample estimations. The resulting difference's positive value implies a higher degree of complementarity for the group of firms above the top quartile. These tests are shown in Table 2.8 (in Chapter 2 Appendix).

Overall, our results confirm our expectations. We find that firms with highly cumulative levels of scientific publications, internal R&D, or patents are characterized, on average, by a higher level of the cross-partial derivative capturing the degree of complementarity. The results confirm that firms with broader experiences across therapeutic areas are characterized, on average, by a stronger complementarity relationship between internal R&D and in-licensing. This finding suggests that these firms may be using knowledge developed in different fields additively in the innovative process, which would support Henderson and Cockburn (1996) view. Finally, results indicate that complementarity increases for firms that have a larger stock of prior licensing deals, which possibly indicates that higher levels of experience in licensing

agreement formation facilitate the management and integration of external technologies (Hoang and Rothaermel, 2010).

2.6. Conclusion

Our goal has been to offer a deeper understanding of the exact nature of the relationship between internal R&D and in-licensing (external R&D). While the extant literature remains unclear about the relationship between these two strategies, our primary focus is to understand how the joint effect of two activities varies across several different drivers. Excluding the research by Cassiman and Veugelers (2006), there is a lack of empirical work examining the conditions under which internal R&D and in-licensing are either complements or substitutes.

We analyze possible determinants of this relationship by splitting our sample based on five potential drivers. Our mean tests confirm that complementarity appears to increase when associated with higher levels of the selected drivers. In other words, firms with higher absorptive capacity, those with alliance experience, and those that enjoy economies-of-scope are characterized by stronger complementarity. These results are confirmed by our graphical analysis and tests of hypotheses, which support a positive relation between complementarity and drivers. Existing theories offer theoretical support of our results and provide insights for further theoretical work on the complementarity between innovative activities. At the same time, we provide a methodological contribution, since our framework can be used for a more rigorous understanding of the industry and firm characteristics that affect the relationship between internal and external innovative activities.

One limitation of this research comes from the fact that we only analyze one dimension of innovative performance, the introduction of new drugs. In line with the contribution of Arora and Gambardella (1994b), for example, one could claim that absorptive capacity, in particular a firm's scientific capability, will allow the technology buyer to be more discerning in the external technology that they select and will have a higher threshold value for each external R&D project. In other words, the mix of internal and external R&D may affect the expected value of an innovation, which we do not observe. To the extent that we are neglecting a potentially positive effect of the mix of internal and external R&D on the profitability of new drugs, our analysis can be considered as providing estimates of complementarity that are downward biased. This may contribute to explain why on average we do not find complementarity. In order to more fully analyze the marginal returns from internal and external R&D we would need data on the profitability associated with each drug, a task we leave for future work.

A second limitation of our study relates to our industry setting and the generalization of our results to other industries, since innovation factors are often determined by industrial dynamics. The R&D process in the pharmaceutical industry is characterized by long development cycles, high costs, and significant levels of uncertainty, which may affect the extent to which a firm relies on different innovative strategies. Industries that present a different innovative process might experience a different relationship. Although our results are not generalizable, our methodology can be replicated in different industry settings.

A third limitation lies in the definition and treatment of uncertainty associated with the drug development process. Recent research presents contrasting results about the

possibility of success correlated to internally developed or externally acquired compounds. For example, Guedj (2005) shows that alliance projects are 21% more likely to move from Phase I to Phase II, while co-developed compounds are less successful in later stages (Phase II, Phase III, and FDA approval) than internal projects. Conversely, Arora *et al.* (2009) suggest that asymmetric information and market imperfections increase costs, and the expected value of the licensed compound increases as a result. They show that the probability of success for a licensed compound is higher than for an internally developed one. We attempt to deal with the uncertainty related to in-licensing investments by controlling for the percentage of in-licensed compounds in each phase. We also weight the firm's research pipeline by the average probability of success associated with each development stage to account for process development uncertainty.

Finally, while our results help us to understand the relation among innovative factors, we do not directly test whether there might be an optimal balance between R&D strategies, as suggested by other scholars. For example, Rothaermel *et al.* (2006) suggest that by performing some activities of the value chain internally and some externally, a firm is able to exploit external technology and adopt a flexible strategy to introduce new products. Knowing whether internal development and in-licensing are complements or substitutes might help build a feasible equilibrium between these two strategies. This would allow for a more complete understanding of the proposed outsourcing move by companies such as GlaxoSmithKline (Knowles and Higgins, 2011). Ultimately, this knowledge also allows for a deeper understanding of the feasibility of more radical views of the innovative process, such as the search and development model proposed by Morgan Stanley (2010) or the vertical integrated structure introduced by Pisano (2006).

CHAPTER 2 APPENDIX

Table 2.2. Descriptive Statistics

Variable	Mean	Std. Dev.	Min	Max
Product pipeline	1.764	1.184	0	5.029
In-Licensing (deflated, Mil. $)	239.443	633.850	0	5184.333
Internal R&D (deflated, Mil. $)	1345.112	3195.205	0.473	28756.440
Detailing stock (deflated, Thousands $)	7042.601	19559.700	0	173521.400
Trademark stock	11.590	34.003	0	426
Expected market size (deflated, Thousands $)	2158.068	1556.527	0	10217.840
Competitors	1308.882	578.575	201	2626
Drug novelty	0.154	0.185	0	1
Sales (deflated, Mil. $)	4510.527	10029.110	0	67674.560
Firm size (hundreds)	13.841	26.717	0.001	122
Scientific References	3.689	3.785	0	36
North America	0.849	0.359	0	1
Europe	0.116	0.320	0	1
Other	0.035	0.184	0	1
Number of ATCs	6.781	5.782	1	16
% licensed compound (Phase 1)	0.029	0.076	0	1
% licensed compound (Phase 2)	0.055	0.129	0	1
% licensed compound (Phase 3)	0.056	0.139	0	1
Main therapeutic areas				
ATC A	0.112	0.316	0	1
ATC B	0.023	0.151	0	1
ATC C	0.095	0.294	0	1
ATC D	0.066	0.249	0	1
ATC G	0.050	0.217	0	1
ATC H	0.005	0.072	0	1
ATC J	0.102	0.302	0	1
ATC K	0.009	0.095	0	1
ATC L	0.043	0.203	0	1
ATC M	0.031	0.174	0	1
ATC N	0.145	0.352	0	1
ATC P	0.001	0.036	0	1
ATC R	0.061	0.240	0	1
ATC S	0.030	0.171	0	1
ATC T	0.009	0.095	0	1
ATC V	0.013	0.114	0	1

N=767

Table 2.3. Correlation Table

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1. Product pipeline	1														
2. In-Licensing (deflated, Mil. $)	0.492	1													
3. Internal R&D (deflated, Mil. $)	0.629	0.733	1												
4. Detailing stock (deflated, Thousands $)	0.642	0.783	0.937	1											
5. Trademark stock	0.338	0.549	0.668	0.597	1										
6. Expected market size (deflated, Thousands $)	0.109	0.090	0.156	0.110	0.096	1									
7. Competitors	0.054	0.163	0.167	0.169	0.092	0.179	1								
8. Drug novelty	-0.069	0.039	0.023	0.020	0.017	0.264	-0.049	1							
9. Sales (deflated, Mil. $)	0.543	0.453	0.738	0.622	0.493	0.249	0.166	-0.045	1						
10. Firm size (hundreds)	0.640	0.493	0.809	0.680	0.542	0.244	0.142	-0.036	0.902	1					
11. Scientific References	0.301	0.217	0.239	0.214	0.177	-0.041	-0.020	-0.044	0.177	0.251	1				
12. Number of ATCs	0.649	0.398	0.499	0.513	0.322	0.195	0.177	-0.135	0.580	0.638	0.218	1			
13. % licensed compound (Phase 1)	0.157	0.137	0.129	0.103	0.121	0.162	0.154	0.004	0.085	0.119	0.084	0.100	1		
14. % licensed compound (Phase 2)	0.072	0.086	0.097	0.068	0.049	-0.010	0.127	0.049	0.100	0.115	0.007	0.103	0.023	1	
15. % licensed compound (Phase 3)	0.043	0.037	0.031	0.019	0.028	0.008	0.027	-0.077	0.059	0.062	0.023	0.065	0.049	0.054	1

Table 2.5. Panel Regressions. Dependent Variable: log(1+Pipeline).

	GMM Fixed Effect				Panel RE	Panel FE
	(1)	(2)	(3)	(4)	(5)	(6)
Log(R&D)	1.181	1.240*	1.078**	0.771**	0.178**	0.209***
	(0.781)	(0.671)	(0.438)	(0.343)	(0.0738)	(0.0722)
Log(Licensing)	-0.355	-0.143	-0.203	-0.169	0.0436	0.00750
	(0.306)	(0.345)	(0.257)	(0.180)	(0.0452)	(0.0427)
$(\text{Log R\&D})^2$	-0.136	-0.0822	-0.0696	0.0118	0.00357	-0.00945
	(0.126)	(0.0935)	(0.0709)	(0.0631)	(0.00826)	(0.00868)
$(\text{Log Licensing})^2$	0.158	0.244*	0.243**	0.143**	-0.00597	-0.0107*
	(0.127)	(0.141)	(0.109)	(0.0687)	(0.00588)	(0.00607)
Log(R&D)* Log(Licensing)	-0.0715	-0.228	-0.221*	-0.150	-0.00110	0.0103
	(0.126)	(0.162)	(0.122)	(0.0931)	(0.00935)	(0.00846)
Publications		-0.0853	-0.0428	0.0251	0.0182	-0.0157
		(0.204)	(0.140)	(0.0923)	(0.0289)	(0.0291)
% compound licensed–Phase I		1.269	1.287	0.823	0.409*	0.443*
		(0.876)	(0.786)	(0.569)	(0.220)	(0.229)
% compound licensed–Phase II		-0.137	-0.0646	0.335	0.147	0.212
		(0.609)	(0.534)	(0.307)	(0.152)	(0.146)
% compound licensed–Phase III		-0.848	-0.757**	-0.523*	0.287*	0.380***
		(0.617)	(0.378)	(0.301)	(0.148)	(0.144)
Firm Size		0.0546*	0.0487**	0.0160	-0.0007	-0.001
		(0.0323)	(0.0244)	(0.0144)	(0.002)	(0.002)
North America					0.453	
					(0.290)	
Europe					1.162***	
					(0.357)	
Number of ATC					0.067***	
					(0.017)	
Firm Fixed effect	Yes	Yes	Yes	Yes	No	Yes
ATC dummies	No	No	Yes	Yes	Yes	Yes
Time dummies	No	No	No	Yes	Yes	Yes
Observations	623	623	623	623	767	767
Log-Likelihood	-556.2	-693.7	-676.6	-470.7		-106.3
Cluster	73	73	73	73	92	92
Over-identification test (p-value)	0.530	0.753	0.736	0.116		

Clustered standard errors in parentheses. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$. While we use the notation "log" we are utilizing the natural log. We use the natural logs of *Promotion*, *Trademarks*, *Potential product market size*, *Drug novelty*, *Number of competitors*, their logs of square terms, and cross-product of logs as instruments for internal and external R&D and the related non-linear terms. Auxiliary first-stage regressions (OLS linear regressions "within" firm) suggest that the instruments have power. Indeed, the F-test of the joint effect of the instruments on each endogenous variable are 3.44, 5.05, 1.57, 16.55, 6.85 for R&D, the log of R&D-squared, licensing, the log of licensing-squared, and the cross-product of the logs of R&D and licensing, respectively.

Table 2.7. GMM fixed-effects regressions on split samples based on absorptive capacity levels. Dependent variable: log(1+pipeline).

	(1) Bottom 25% Publication	(2) Top 25% Publication	(3) Bottom 25% R&D	(4) Top 25% R&D	(5) Bottom 25% Patent	(6) Top 25% Patent
Log R&D	0.299	1.245***	-1.045	4.500	0.448	-0.804
	(0.556)	(0.402)	(0.847)	(5.962)	(0.355)	(1.055)
Log Licensing	-0.0509	-0.740**	-0.0586	-0.260	-1.092**	0.728
	(0.847)	(0.341)	(0.395)	(1.548)	(0.464)	(0.735)
$(\text{Log R\&D})^2$	-0.0330	-0.108***	0.0978	-0.353	-0.0205	0.0590
	(0.0613)	(0.0417)	(0.0956)	(0.463)	(0.0553)	(0.130)
$(\text{Log Licensing})^2$	0.0683	-0.0394	-0.142	-0.0761	0.348***	-0.0657
	(0.0780)	(0.0518)	(0.165)	(0.0761)	(0.0840)	(0.0655)
(Log R&D)* (Log Licensing)	-0.00359	0.155	0.242	0.178	-0.272***	0.0325
	(0.107)	(0.101)	(0.212)	(0.286)	(0.0936)	(0.163)
Publications	-0.227	-0.488*	-0.163	-0.228***	0.151	0.112
	(0.159)	(0.272)	(0.180)	(0.0543)	(0.172)	(0.305)
% compound licensed–Phase I	-0.186**	0.242	-0.254*	-1.658**	0.374***	0.335
	(0.0944)	(0.360)	(0.143)	(0.815)	(0.129)	(0.804)
% compound licensed–Phase II	0.325**	-2.224***	0.590***	-1.794***	1.951***	-1.587***
	(0.159)	(0.342)	(0.176)	(0.386)	(0.522)	(0.492)
% compound licensed–Phase III	0.678**	-2.203***	0.713*	-2.249***	0.0621	-0.904
	(0.328)	(0.456)	(0.371)	(0.477)	(0.457)	(0.654)
Firm Size	-0.0289	-0.0000161	-0.202	0.0120	0.00452	-0.00446
	(0.228)	(0.00309)	(0.193)	(0.00843)	(0.0305)	(0.00336)
Firm Fixed Effect	Yes	Yes	Yes	Yes	Yes	Yes
Time Dummies	Yes	Yes	Yes	Yes	Yes	Yes
Observations	93	124	100	124	104	121
Log-Likelihood	-23.80	17.64	-9.087	3.005	-50.59	9.551
Cluster	19	19	29	20	25	20
Over-identification test (p-value)	0.692	0.330	0.186	0.700	0.244	0.444

- Standard errors in parentheses. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.
- While we use the notation "log" we are utilizing the natural log.

Table 2.7. GMM fixed-effects regressions on split samples based on economies of scope and licensing experience levels. Dependent variable: ln(1+pipeline) - Continued

	(1) Bottom 25% Number of ATCs	(2) Top 25% Number of ATCs	(3) Bottom 25% Licensing	(4) Top 25% Licensing
Log R&D	0.309	0.554**	0.705	0.113
	(0.508)	(0.246)	(1.440)	(0.492)
Log Licensing	0.956	-0.328*	1.311	-1.473
	(0.585)	(0.176)	(2.634)	(0.901)
(Log R&D)^2	0.152*	-0.0988**	-0.182	-0.143
	(0.0921)	(0.0403)	(0.232)	(0.0936)
(Log Licensing)^2	0.159	-0.0474	-0.282	0.0322
	(0.114)	(0.0340)	(0.204)	(0.298)
(Log R&D)* (Log Licensing)	-0.429***	0.145**	0.264	0.367***
	(0.135)	(0.0708)	(0.526)	(0.128)
Publications	0.417**	-0.216***	-0.421	-0.0794
	(0.187)	(0.0550)	(0.437)	(0.195)
% compound licensed–Phase I	2.014***	0.842	1.072	-0.671
	(0.756)	(0.652)	(1.251)	(0.978)
% compound licensed–Phase II	0.0453	-1.020***	-0.750	0.0285
	(0.357)	(0.393)	(0.888)	(0.291)
% compound licensed–Phase III	-0.564***	-0.642	-1.062	-0.415**
	(0.205)	(0.468)	(0.928)	(0.179)
Firm Size	0.232**	0.00349	0.00940	0.0281
	(0.0970)	(0.00231)	(0.00858)	(0.203)
Firm Fixed Effect	Yes	Yes	Yes	Yes
Time Dummies	Yes	Yes	Yes	Yes
Observations	176	159	111	112
Log-Likelihood	-65.55	7.785	-4.450	10.30
Cluster	25	20	24	26
Over-identification test (p-value)	0.833	0.133	0.416	0.429

- Standard errors in parentheses. * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.
- While we use the notation "log" we are utilizing the natural log.

Table 2.8. Tests on mean complementarity $\left(\frac{d^2n}{dR_i dR_e}\right)$ differences by group of firms.

		Full Sample estimation		Split-sample estimations	
		Mean cross-partial	Standard Error	Mean cross-partial	Standard Error
Publications	<= 25%	**-0.102**	0.029	**-0.00004**	0.0002
	> 75%	**-0.019**	0.001	**0.007**	0.003
	Difference	**0.082****		**0.007****	
Internal R&D	<= 25%	**-0.165**	0.039	**-0.039**	0.005
	> 75%	**-0.018**	0.001	**0.012**	0.007
	Difference	**0.146*****		**0.052*****	
Patents	<= 25%	**-0.063**	0.026	**-0.032**	0.026
	> 75%	**-0.017**	0.0006	**0.059**	0.004
	Difference	**0.046****		**0.092*****	
Number of ATC	<= 25%	**-0.093**	0.02	**-0.317**	0.045
	> 75%	**-0.045**	0.008	**0.0012**	0.0002
	Difference	**0.047****		**0.318*****	
Licensing experience	<= 25%	**-0.218**	0.039	**-0.077**	0.016
	> 75%	**-0.016**	0.0005	**0.019**	0.002
	Difference	**0.202*****		**0.09*****	

- The table contains estimates of the cross-partial $\frac{dn^2}{dR_i dR_e}$ obtained using the GMM estimates from tables 6 and 7.
- The table shows one tail tests.
- ***, **, * indicate that the difference is < 0 at the 0.01, 0.05 and 0.1 confidence levels, respectively.
- A positive mean difference suggests that firms above the top quartile of the distribution of the examined driver experience higher level of complementarity between internal and external R&D.

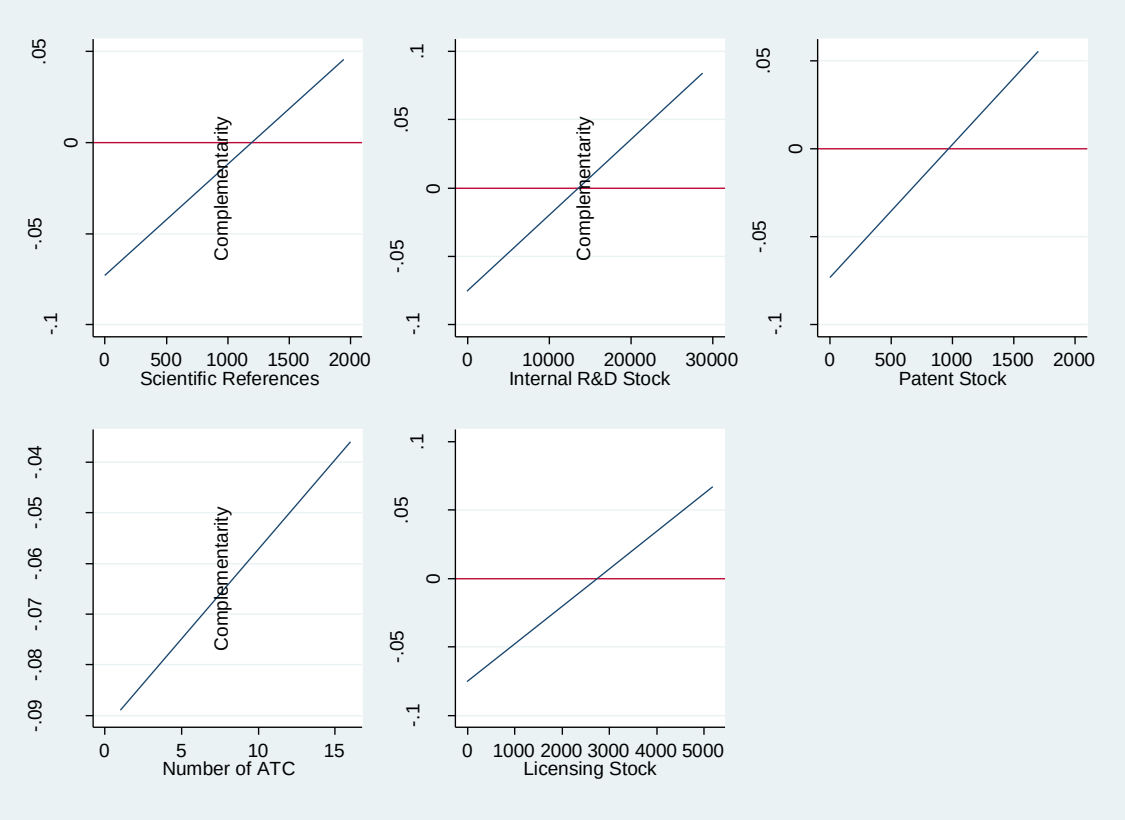


Figure 2.1. Distribution of complementarity across drivers

CHAPTER 3

INTERNAL KNOWLEDGE ACCUMULATION AND THE ACQUISITION OF EXTERNAL TECHNOLOGY: IS THERE A TRADE-OFF?

3.1. Introduction

The mechanism behind the combination of internal and external knowledge is still an open and interesting topic in the strategy literature. Prior work has focused on understanding how firms integrate internal and external knowledge and how they benefit from their adoption (Cassiman and Veugelers, 2006; Cohen and Levinthal, 1990; Katz and Allen, 1982), while a different stream has emphasized the importance of structural organization and resource distribution in the case of acquisitions (Ahuja and Katila, 2001). Surprisingly, there is still little integration between these streams. In particular, there is a lack of attention on organizational behavior and characteristics that may facilitate or limit the adoption of external technologies.

For instance, the existing literature has highlighted the benefits of external technology acquisition for a firm's innovative output (Arora and Gambardella, 1990; Cassiman and Veugelers, 2006; Ceccagnoli *et al.*, 2011), but there is little understanding on (1) how the exploitation of internal knowledge affects the adoption of the acquired technologies and (2) how the effect of organizational characteristics moderates this relationship. Specifically, companies may extensively rely on their internal knowledge and capabilities, thereby isolating themselves from external ideas. This attitude has been defined by Cohen and Levinthal (1990) as inward-looking behavior. Under these circumstances, the adoption of acquired technologies imposes a comparison with existing

knowledge that may be considered superior. As a consequence, employees, working teams and communities may respond to this comparison with resistance and bias toward external knowledge. This attitude may lead to the Not Invented Here (NIH) syndrome (Clagett, 1967; Katz and Allen, 1982), which refers to the negative bias toward knowledge developed outside the focal institution. Innovation and strategy literature has greatly overlooked this phenomena, while practitioner papers have identified this trade-off as an important factor in the conversion from closed to open forms of organization (Chesbrough, 2006). For example, Huston and Sakkab (2006) report the following about P&G's transition from the classic R&D model to the innovative Connect and Develop model:

> "We needed to move the company's attitude from resistance to innovations "not invented here" to enthusiasm for those "proudly found elsewhere". And we needed to change how we defined, and perceived, our R&D organization – from 7500 people inside to 7500 plus 1.5 million outside, with a permeable boundary between them." *(p.61)*

In addition to analyzing the negative bias toward external technologies, this paper aims to identify two potential moderating factors: the level of absorptive capacity and the level of organizational decentralization. The former represents the knowledge base of the company and it plays an important role in the selection of external knowledge; it has also been linked to higher benefits associated with technology ambidexterity, and it functions as a bridge with the external environment (Reagans and McEvily, 2003; Rothaermel and

Alexandre, 2009). The latter refers to the decision to adopt a centralized or decentralized R&D organizational structure. Centralized firms may create a competitive environment between internal and external knowledge because the decision to acquire external knowledge is made directly by the headquarters of the company. This competitive environment may favor a contraposition between internal and external knowledge, thus supporting the rise of inward-looking behavior.

The contribution of this study is twofold. First, it fills a gap in the literature on firm boundaries and knowledge management. It analyzes the possibility of internal knowledge substituting for external technologies. This negative effect can be associated with the inward-looking behavior of the firm and the NIH syndrome. As argued by Katz and Allen (1982), inward-oriented organizations may perceive external knowledge as inferior or as a potential threat when compared to internal knowledge. It is important to understand the extent to which such organizations are more likely to reject the adoption of external technologies. Second, this study emphasizes the role played by two contingent factors in mitigating the negative bias toward external knowledge. I suggest a 2X2 matrix that classifies firms based on their level of absorptive capacity and their organizational structure (centralized vs. decentralized).

My findings expand existing literature and prior results. I find that the joint effect of internal knowledge and licensing acquisition is negative, which suggests that the two sources of knowledge are substitute and supports the logic behind the inward-looking behavior argument. Firms that primarily exploit their internal knowledge develop a negative attitude toward external technologies. The central argument is that firms are more successful when they are able to combine different sources of knowledge. But

specialization in the use of internal knowledge increases the cost of adopting knowledge developed outside the firm's boundaries; when the integration cost is too high, the adoption of external knowledge is reduced. I also find support that organizational structure and absorptive capacity affect and mitigate inward-looking behavior. Results suggest that firms can reduce negative bias and benefit from an open strategy through a high level of absorptive capacity and the adoption of a decentralized structure.

3.2. Theory and hypotheses

This paper draws upon several existing streams of literature that have explored the decisions and benefits associated with external knowledge and its integration within the company. The first stream refers to the literature regarding firms' boundaries. This stream of research suggests that innovative firms should exploit external knowledge to increase their performance, but it assumes that acquired technologies are integrated in the organization and firms are able to benefit from them. This assumption may be restrictive, since existing values and routines may limit the adoption of external technologies. To address this gap on technology adoption, I rely on a second stream of research, regarding internal organization. External technology adoption can be influenced by several organizational factors such as communication channels, routines and individual incentives. I focus on the negative bias that firms may have toward external technologies because they adopt an inward-looking behavior. It is possible that firms are not able to successfully exploit the acquired knowledge because of their negative attitude resulting from phenomena such as in-group favoritism and the NIH syndrome which, as previously mentioned, is defined as the rejection of external ideas by a group that believes it

possesses a monopoly in its knowledge field (Katz and Allen, 1982). Finally, I exploit research on decentralization and innovation to define two organizational factors that mitigate the inward-looking behavior of the company.

Existing literature has mainly applied two different theories to describe and predict a firm's boundary: the capability-based view and the transaction cost theory. The former proposes that a firm's choice is driven by the level of complementary, internal capabilities and external knowledge (Kogut and Zander, 1993), while the latter advocates that the boundary choice is based on the comparison of the costs sustained to develop the knowledge either internally or externally (Williamson, 1975).

Transaction cost economics suggests that two issues are relevant in determining a firm's boundary: the cost of governance and the threat of opportunism. In general, lower transaction costs favor the adoption of a market governance rather than a hierarchical one. However, firms should also consider the threat of opportunism in an exchange, due to transaction-specific investments. Opportunism arises when a party involved in the transaction is able to gain an advantage over the other party. According to the transaction cost logic, firms that need to access new capabilities should choose between internalization and market acquisition based on the level of transaction-specific investment. If these investments are high, then internal development should be favored as a form of governance.

However, transaction cost theory has a limitation: it assumes a substitute relationship between knowledge sources, despite recent evidence that has demonstrated the importance of managing both the "make" and "buy" decisions simultaneously (Parmigiani, 2007). For this reason, firms usually need to integrate their existing

capabilities with external knowledge through licensing, outsourcing and acquisition (Arora and Gambardella, 1990; Cockburn and Henderson, 1998). In such a dynamic environment, corporations are forced to adapt and shape their boundaries both by developing new technologies internally and by acquiring them from external sources.

Recent studies suggest that companies should develop skills in both internal development and external sourcing to develop dynamic capabilities and survive over time. For example, Agarwal and Helfat (2009) point out that firms are required to successfully undertake both internal and external knowledge development to successfully implement strategic renewal. Under this view, acquisitions, alliances and licensing agreements help reduce the obsolescence of existing capabilities and encourage the acquisition of knowledge to fill existing internal knowledge gaps (Capron and Mitchell, 2009; Rosenkopf and Nerkar, 2001). Evidence also demonstrates that firms can benefit from technology acquisition by increasing the size of their acquired knowledge base (Ahuja and Katila, 2001) or exploiting information about a target's innovative activity prior to the acquisition (Higgins and Rodriguez, 2006). Finally, firms can effectively adopt external sourcing modes to build new capabilities and boost their performance through concurrent sourcing, defined as the simultaneous choice of making and buying (Parmigiani, 2007).

Firms that engage in both internal production and external acquisition of knowledge may experience synergies between different knowledge sources. Complementarity between internal and external innovative efforts suggests that different sources of knowledge modes are mutually dependent. In other words, this implies that there are synergies between knowledge-generating activities. It follows that, when

complementarity emerges, firms that acquire external knowledge must also continue to engage in internal R&D to remain competitive (Agarwal and Helfat, 2009; Chesbrough, 2003). It is widely accepted that complementarity influences a firm's propensity to access external knowledge (Arora and Gambardella, 1994a; Cassiman and Veugelers, 2006) through several modes such as licensing, alliances and acquisitions (Arora and Gambardella, 1990; Cockburn and Henderson, 1998).

One limit of this stream of research is the assumption that organizations are able to internalize the acquired knowledge and benefit from it. However, it may be possible that internal-organization factors reduce the adoption of external knowledge. I aim to fill this gap by integrating the literature on firms' boundaries with research on internal organization. More precisely, I focus on the role of internal knowledge as a potential mechanism that affects the adoption of external knowledge.

The combination of internal knowledge and external technologies has been linked to a lower innovative performance. Hoang and Rothaermel (2010) and Rothaermel and Alexandre (2009) support the idea that firms face a trade-off between internal and external technology sources. The former research suggests that, in the context of biotechnology firms when companies combine internal technology exploitation with external exploration, the negative effect on the performance of R&D projects is higher. The latter paper, offering a similar perspective, empirically shows that the relation between different technology sources is nonlinear; it follows an inverted-U-shaped distribution. A similar nonlinear relation was empirically tested by Laursen and Salter (2006) with a sample from the U.K. innovation survey that includes all main sectors of the U.K. economy. The authors suggest that companies need to balance their openness to

external sources. Indeed, the lack of an open strategy may lead them to excessively rely on internal knowledge and to underemphasize external knowledge, thus reducing the ability to exploit innovative opportunities. The opposite behavior can be detrimental as well; firms may focus more on their search for external technologies than the development of internal capabilities. As a consequence, the innovative performance may be hindered because of the effect of over-searching (Katila and Ahuja, 2002).

These results suggest the possibility of a trade-off between internal and external knowledge sources. Although theoretically possible, it is unlikely that firms specialize exclusively in either internal or external technologies because most firms, across several industries, have increasingly adopted an open-innovation approach (Chesbrough, 2003, 2006; Laursen and Salter, 2006). However, this approach does not exclude the possibility that firms need to reshape and adapt their organizations to successfully balance internal and external technologies.

One challenge that might arise from the reorganizational process is the tension between internal and acquired knowledge. In fact, if internal knowledge is considered superior, companies can reject new ideas and, consequently, reduce their performance. While some overlap of knowledge within the company favors information sharing and is necessary for internal communication, there are benefits associated with having a diversity of knowledge sources. This idea is in line with the definition of inward-looking behavior introduced by Cohen and Levinthal (1990). The authors suggest that the concept of absorptive capacity can be divided into two different components: the outward-looking and the inward-looking absorptive capacities. The former refers to the excessive reliance on external knowledge, which reduces and deteriorates the development of internal

capabilities. This concept is consistent with the effect of over-searching described by Katila and Ahuja (2002) and Laursen and Salter (2006). The latter component reflects the specialization in internal knowledge and the potential rejection of external sources. Firms may underestimate the importance of external knowledge because they overemphasize the role of internal technologies. This behavior facilitates the formation of routines and communication mechanisms, but it introduces a negative bias toward external knowledge. In particular, the negative effect can be linked to the disruptive role that external sources may have on existing internal mechanisms and routines. Under these conditions, firms may implement an inward-oriented knowledge accumulation (IOKA) process that extensively relies on internal knowledge: this process exploits the cumulated knowledge of the firm, and it is based on routines, norms, and lower costs of access that may induce firms to discount acquired technologies.

It follows that an inward-oriented process may be detrimental for the company. For example, the assimilation of external knowledge requires companies to accept and to adapt existing capabilities, but inward-looking behavior can negatively influence this process. Indeed, if internal knowledge becomes very specialized, it impedes the assimilation of outside knowledge; as a result, the inward-looking attitude may generate the NIH syndrome (Katz and Allen, 1982). As a consequence, those companies afflicted would be more likely to substitute internal technologies for external knowledge sources.

Most prior work has referred to the NIH syndrome as a theoretical concept and has emphasized the negative effects associated with it. A pioneering contribution to the analysis of the NIH syndrome is represented by the work of Clagett (1967). He analyzed four different case studies in which several plants adopted process innovations developed

by the R&D unit. Two factors were identified as antecedents of the NIH syndrome: violation of the norms and routines of the organizational unit, and resistance to changes in a familiar environment. Both factors generate a negative attitude toward knowledge and reduce the adoption of external technologies. After surveying several R&D professionals in 50 project groups, Katz and Allen (1982) found similar results to those of Clagett (1967). The NIH syndrome is generated by the insecurity and environmental instability created by external technology. In particular, new knowledge affects and changes existing routines and roles, creating instability. As a result, project performance diminishes when teams operate in a stable collaborative environment for more than five years.

Knowledge creation is a complex process involving individuals, beliefs and information. The combination of these factors creates an internal system of routines that supports process information and problem solving (Nelson and Winter, 1982). These routines are often tacit and developed over time, making them difficult to imitate and transform (Teece *et al.,* 1997). External knowledge can threaten the existing internal status quo among an organization's community. If individuals feel that their contribution to the knowledge-generating process is being threatened, then they may slow the adoption of new technologies and treat external knowledge with hostility.

The IOKA process and the NIH syndrome are also consistent with the mechanisms and outcomes associated with in-group favoritism: a confrontation with acquired technologies may create instability between internal and external knowledge. A greater level of identification with the company implies a stronger bias in favor of internal knowledge and a higher perceived threat of external knowledge. Although strong

in-group favoritism may have positive effects on firm activities (Gioia *et al.*, 2000), it can also favor in-group bias toward ideas generated outside the group. For example, socialization practices help preserve in-group favoritism and create negative biases against out-group knowledge (Burcharth and Fosfuri, 2012).

As suggested by research on inward-looking behavior, in-group favoritism, and the NIH syndrome, internal-knowledge reliance may substitute for external knowledge. As a consequence, this negative behavior can lower the effectiveness with which external technologies are integrated within a firm's value chain. Therefore, I consider the following hypothesis:

H1. An inward-oriented knowledge accumulation (IOKA) process within the firm reduces the marginal effect of investments in external knowledge on firm performance.

To fully understand the performance implication of the inward orientation of the firm, I focus on two conditioning factors that may affect the interaction between internal-knowledge reliance and external technology. It is crucial to identify the context in which the negative bias may be stronger or weaker. I highlight organizational and technological capabilities as two drivers that might affect the impact of inward-looking behavior. More precisely, I propose that the level of absorptive capacity and the decentralization of R&D's organizational structure are factors that may limit or emphasize the negative bias toward external knowledge.

First, the focus on absorptive capacity is justified by the role played by a firm's knowledge base in the selection and assimilation of external knowledge (Cohen and Levinthal, 1990; Cohen and Levinthal, 1989). The integration of external knowledge is influenced by the level of absorptive capacity; thus, the negative effect of inward-looking behavior depends on the company's knowledge base. High levels of absorptive capacity do not necessarily imply that the NIH syndrome cannot occur, due to the fact that inward-looking firms may still fail to understand the potential of external knowledge. As a consequence, firms may not effectively integrate and use the acquired knowledge. However, firms with higher absorptive capacity should be able to reduce the uncertainty and bias toward external knowledge and, therefore, should not have a strong negative attitude toward acquired knowledge (Lichtenthaler and Ernst, 2006). This process differs from IOKA: absorptive capacity doesn't directly compare internal and external knowledge sources since firms use their knowledge base to evaluate external knowledge, while IOKA directly contrasts them, creating possible tension. In fact, absorptive capacity reduces uncertainty and identifies potential synergies with existing knowledge, whereas IOKA refers to the preference of adopting the stock of internal knowledge instead of the acquired one.

Indeed, absorptive capacity reduces the level of uncertainty related to external knowledge (Cohen and Levinthal, 1990; Volberda *et al.*, 2010). If firms are able to better understand external technologies, they may also better assess their quality and their overlap with internal knowledge. In other words, absorptive capacity influences the perception and accessibility of external knowledge. As shown by Rothaermel and Alexandre (2009), absorptive capacity positively moderates a firm's technology strategy

that combines internal and external sources. Their results suggest that a firm's knowledge base facilitates the balance between internal and external technologies, thus reducing the contraposition arising from inward- and outward- looking behaviors. Firms can leverage their knowledge base to bridge across knowledge boundaries and increase their performance (Reagans and McEvily, 2003).

It follows that higher levels of absorptive capacity facilitate knowledge evaluation, therefore mediating between the perceived superiority of internal knowledge and the potential threat posed by external sources. Firms with higher levels of absorptive capacity will be able to better evaluate the potential synergies and the risks associated with the acquisition of external knowledge. In other words, absorptive capacity increases the overall level of information about the acquired knowledge, making it less ambiguous; as a result, the internal knowledge base sheds light on the quality and applicability of the knowledge. Inversely, the lack of absorptive capacity facilitates biased perceptions of external knowledge, thus favoring attitudes such as inward-looking behavior, in-group favoritism and the NIH syndrome. Following this reasoning, I expect that the negative bias toward external knowledge will be mitigated by absorptive capacity. As a result, I suggest the following hypothesis:

H2. Absorptive capacity moderates the relationship between an inward-oriented knowledge accumulation (IOKA) process and investments in external knowledge.

Second, I suggest that the level of organizational decentralization can affect the bias toward external technologies. Previous research has found that firms that focus on basic research adopt a more centralized R&D structure, whereas those that focus on applied and incremental research adopt a decentralized organization (Argyres and Silverman, 2004). The paper by Argyres and Silverman (2004) opens an important discussion on how R&D organization affects the direction and the importance of technology investments. My study aims to expand their findings in several ways. First, I focus on the impact of decentralization on a firm's value rather than a firm's innovative performance. Second, I consider the level of decentralization used as a moderating role between the exploitation of internal knowledge and the acquisition of external knowledge. Finally, Argyres and Silverman (2004) define external research in terms of how much the focal firm cites external patents, but they discount the importance of the acquisition of external technologies through mechanisms like M&A and licensing; I link the role of organizational structure to the adoption of licensed technologies using a value function approach.

Arora *et al.* (2013b) define firms as decentralized when their internal business units are involved in the licensing decision, and centralized when their internal business units are not involved in the licensing decision.[12] The effect of centralized and decentralized firms on the inward-looking attitude relies on the trade-off between private information about the external technology and economic incentives. Internal business

[12] In my data I don't directly observe whether a business unit is involved in the licensing process, but I rely on patent assignment to define the level of decentralization. The underlying assumption is that patents are often assigned to either the parent company or its affiliates and that patent ownership may reflect involvement in the technology acquisition process. I acknowledge that there may be corporate policies that assign patents ownership regardless of the organizational structure. I discuss the validity of this measure in detail in Section 3.3, "Empirical data and methodology."

units may have superior knowledge and information about licensed technologies, while a centralized licensing unit may focus more on the economic incentives connected to licensing opportunities. As a consequence, the technology source mix differs among these two different type of organizations: centralized firms rely more on internal R&D, whereas decentralized companies exploit more external knowledge (Arora *et al.*, 2013a).

In the case of centralization, the licensing decision is imposed by the dedicated unit to the focal business unit. As a consequence, the acquired knowledge may be not adequately integrated because of two factors that facilitate a negative attitude toward external knowledge: the acquisition of substitute technologies and the allocation of R&D resources. Since the selection of the external technology is decided by the centralized licensing unit, the new technology may substitute for internal knowledge, in which case the external technology may work against the interest of the business units. Internal incentives such as internal unit productivity may limit the adoption of external technology because it is perceived as a threat (Katz and Allen, 1982). In addition, the acquisition of external technologies can reduce the resources available for internal research and diminish incentives for innovation (Hitt *et al.*, 1990). For example, in 2009, GlaxoSmithKline diverted some of its internal resources toward a more open strategy: the company divested its neuroscience program in order to allocate 50% of its R&D budget to external projects (Knowles and Higgins, 2011). Moreover, the reduction of funds for the internal unit led to a reduction of both the monetary and non-monetary incentives (Hitt *et al.*, 1990; Stern, 2004). Based on these arguments, it follows that centralized firms are more likely to manifest inward-looking behavior and express a negative attitude toward external technologies.

Alternatively, decentralized companies do not impose the decision to buy external technologies and they do involve business units in the acquisition process. The joint effort between headquarters and business units creates a cooperative environment that should favor the adoption of external technologies. Since business units are directly involved in the procurement decision, they may perceive external knowledge as less threatening because the business units experience a higher level of decision-making freedom compared to centralized organizations. Even in the case of decentralization, however, the resource reallocation problem may be present. To solve this issue, Arora *et al.* (2013b) suggest that the business unit share both the cost and the profit of the acquired technology. This strategy should align the information and economic incentives of both the business unit and the corporate headquarters. It follows that decentralization should reduce the negative bias toward external knowledge and mitigate the negative effect of inward-looking behavior.

In summary, centralization favors a contraposition and direct comparison between internal and external knowledge; this process should favor the development of the negative bias toward acquired knowledge. Conversely, decentralization favors a more cooperative organizational environment: subsidiaries have the freedom to invest in the technologies that best fit their necessities. In addition, when firms adopt a decentralized structure, subsidiaries can play the role of knowledge gatekeepers between the external environment and the organization. Past research has identified them as possible mechanisms that firms can use to manage and reduce biases introduced by inward-oriented knowledge (Katz and Allen, 1982; Lichtenthaler and Ernst, 2006). As a result, the following hypothesis should hold true:

H3. Higher levels of decentralization moderate the relationship between an inward-oriented knowledge accumulation (IOKA) process and investments in external knowledge.

3.3. Empirical data and methodology

I test the hypotheses on an unbalanced panel of 92 pharmaceutical companies that were active between 1997 and 2008. The sample is based on a unique dataset built from a variety of sources. First, I identified all the companies listed in the FDA Orange Book that had an approved drug. Next, these companies were matched to the Deloitte-ReCap database to collect data on licensing investment and external technology acquisition (e.g., royalties, up-front payments and milestones). Data on R&D productivity and drug development (e.g., the various stages of clinical trials, FDA approval and project discontinuations) was collected from Pharmaprojects.

Data on total R&D expenditures and the number of firm employees was collected from Compustat. Sales from new products and advertising expenditures were obtained from IMS MIDAS™. The promotion data includes investments directed toward physicians and hospitals, journal advertising and direct-mail to promote drugs. Finally, granted patents were collected from the United States Patent and Trademark Office (USPTO) patent database to build citation measures. As described by Graham and Higgins (2007), I limited my analysis to pharmaceutical-related patents in the international technology classes A61K and C07D. Patents listed in these two international technology classes identify technologies related to pharmaceutical products; they exclude non-pharmaceutical innovations such as cosmetics and medical devices. I focused only

on these two patent classes to study the primary outcome of the R&D activity of pharmaceutical firms that relates to drug development. All financial variables are presented in constant 2000 U.S. dollars.

In order to examine the effects of inward-looking behavior, I estimated several panel regressions, including panel random effects, panel fixed effects and panel GMM with fixed effects. The different empirical methods are needed to take potential endogeneity problems into consideration. For all the specifications, I estimate the following equation:

$$(1) \qquad MktCap_{i,t} = \beta_0 + \beta_1 * Lic_{i,t-1} * IOKA_{i,t-1} + \beta_2 * Lic_{i,t-1} + \beta_3 * IOKA_{i,t-1} + + \beta_4 * K_{i,t-1} + \beta_5 * V_i + \beta_6 * Z_t + \epsilon_{it}$$

where $MktCap_{i,t}$ represents the firm value at time *t* for firm *i*. $Lic_{i,t-1}$ and $IOKA_{i,t-1}$ are the licensing investments and inward-oriented knowledge accumulated for firm *i* at time *t-1*, respectively. Finally, $K_{i,t-1}$ includes the linear term of the interacted variables and other firm controls; $V_i \; and \; Z_t$ are firm- and time-fixed effects, respectively; and ϵ_{it} is the error term.

Empirically, the first hypothesis advocates that the cross partial derivative of Equation (1) with respect to licensing and inward-looking behavior is negative. To test the second hypothesis, I divide the sample based on the median level of absorptive capacity and estimate Equation (1) using the two subsamples. To confirm H2, I expect the coefficient β_1 to be larger for firms with high levels of absorptive capacity. I adopt a similar approach to test the third hypothesis and create the two subsamples based on the

median value of the level of decentralization. I expect to find the coefficient β_1 to be larger for decentralized firms.[13]

3.3.1. Dependent variable

The dependent variable in this study, *Market capitalization*, is measured by calculating the product of the average share price and the number of shares outstanding. The data was collected from the COMPUSTAT database. Internal innovative development is an essential driver of firm value because it transforms innovations into final products. Similarly, knowledge acquired externally can strengthen and boost the effect of product development (Chesbrough, 2006). The variable used in the empirical regressions is transformed as $\ln(1+ \text{MktCap}_{i,t})$.

3.3.2. Independent variables

The *Licensing* investment variable is one of the main independent variables, and it represents a firm's external knowledge acquisition. To measure licensing investments, I relied on data collected from the Deloitte-Recap database. My measure includes both up-front and milestone payments. Royalties are not included because they represent a cost based on future sales, and are thus unobservable within the scope of this study. Licensing stock is measured using a perpetual inventory method with a 15% discount factor (Hall *et al.*, 2005) and then transformed using the natural logarithm.

The *Inward Oriented Knowledge Accumulation (IOKA)* variable measures the use and adoption of internal knowledge of the focal firm. This measure represents the degree

[13] The regressions using the subsamples have been tested using the mean value of both absorptive capacity and decentralization. The results are confirmed.

to which the focal firm draws from prior technologies developed internally. Following Hall *et al.* (2005) and Agrawal et al. (2010), the number of all backward patent citations and the number of self-citations were collected. The formula used to measure the adoption of internal knowledge was:

$$IOKA_{it} = \frac{C_{it}^{S}}{C_{it}}.$$

For each company, C_{it}^{S} represents the total number of self-citations (based on assignee) of all patents for firm *i* at time *t*, and C_{it} represents the total number of citations of all patents assigned to firm *i* at time *t*. This measure captures firm *i*'s attitude toward internal knowledge: inward-looking behavior will be high when self-citations represent the majority of total backward citations. Similarly to the licensing variable, *IOKA* is measured as a stock variable with a 15% depreciation rate and is transformed using the natural logarithm.

To account for the size of the patent portfolio, I adopt the ratio of the stock of self-citations to the patent stock as a robustness measure (Hall *et al.*, 2005). Self-citations suggest that a firm has a strong technology position, allowing it to internalize the spillovers generated by its internal R&D projects; however, this effect is linked to the size of the patent portfolio simply because the more patents a firm has, the more likely a new citation is given to a patent that the company already owns (Hall *et al.*, 2005).

I adopt *Publication stock* as a measure of absorptive capacity. As suggested by Cassiman and Veugelers (2006), reliance on more "basic" know-how affects the strength

of the complementarity between internal and external innovation strategies. The variable is computed as the focal firm's cumulative number of scientific publications. To test the robustness of my results, I adopt alternative measures of absorptive capacity: following Arora and Gambardella (1994b), I defined the stock of scientific references (*Scientific references stock*) and the cumulative stock of internal R&D (*R&D stock*) as robustness measures. Based on each of these measures, I create three dummy variables that equal one if the focal firm is above the median value of the absorptive capacity variable. Firms that are above the median values have higher levels of absorptive capacity, so they should be able to better integrate external technologies and mitigate the negative bias introduced by inward-looking behavior.

Following Arora *et al.* (2013a), I construct a measure for R&D decentralization based on patent assignments (*Decentralization*). First, I collected data on the corporate tree structure from the D&B Million Dollar Database. This allows distinguishing between corporate headquarters and corporate subsidiaries. Then I collected and classified the assignee of all patents assigned to the firms in my sample and matched the assignee with either the corporate headquarters or the subsidiaries. I classify individual patents as decentralized if the patent ownership is assigned to one of the firm's affiliates. Third, I estimated the yearly percentage of decentralized patents for each firm. Values closer to one suggest that the firm adopts a decentralized R&D organizational structure and that it delegates a certain level of autonomy over R&D management to its subsidiaries. The distribution of several self-citation measures as proxy of inward-looking behavior for both centralized and decentralized firms is displayed in Figure 3.1. The difference in inward-looking behavior between the two groups is readily apparent significant at the 1%

level. The non-parametric results are in line with the theoretical predictions that decentralized firms should suffer less from inward-looking behavior.

In addition, the data confirms a pattern of organizational structure for firms whose organization is well known. For example, Abbott Laboratories and Eli Lilly assign about 10% and 5% of their patents to subsidiaries, respectively. These two firms have been traditionally associated with centralized organizations (Mayer, 2003). Similarly, Pfizer assigns about 95% of its patents to the corporate headquarter, which is consistent with the known hierarchical structure of the company (Hill and Jones, 2012, p. 356). A contrasting example is provided by Johnson & Johnson, which is renowned for its decentralized-management approach.[14] In my data only a small percentage of patents (about 3%) is assigned to the corporate headquarter.

Finally, Arora *et al.* (2013a) compare their measure with the one adopted by Argyres and Silverman (2004). They were able to match 56 of the 71 firms in Argyres and Silverman (2004); 70% of them were perfectly coded as either centralized, hybrid or decentralized. Overall, the adoption of patents to determine the level of decentralization may present some limitations: it is possible that patent assignments are defined by corporate policy, regardless of the actual organizational structure. Argyres and Silverman (2004) used data on R&D funding at both the corporate and the R&D unit level to code the level of decentralization. While their approach may be more reliable, it is based on survey data, making it difficult to replicate. The use of patents has three advantages: (1) it

[14] http://www.jnj.com/about-jnj/management-approach (last accessed: 08/05/2013)

is based on observable factors, (2) it is easy to replicate and (3) it can be applied to both large and small samples (Arora *et al.*, 2013a).[15]

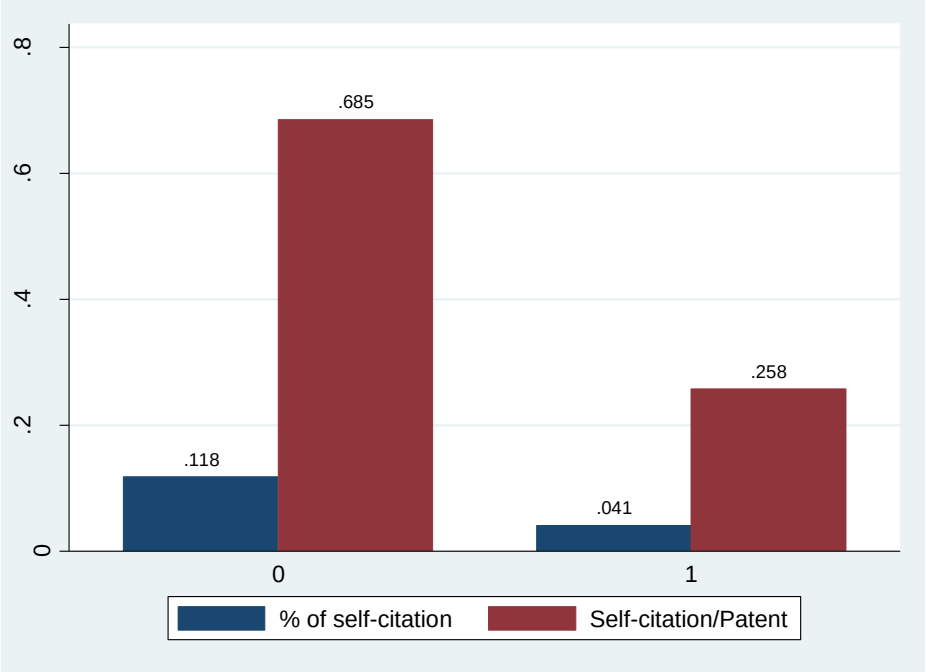


Figure 3.1 Relationships between Inward-Looking Behavior and Decentralization

3.3.3. Instrumental variables

In order to deal with the potential endogeneity introduced by licensing investments, I used several variables as instruments in the GMM estimations. I used

[15] See Arora *et al.* (2013a) for a complete discussion on the advantages and limitations of this measure.

trademarks, average drug novelty, the number of competitors, the development speed of compounds in the pipeline and the expected market size of the average product in the pipeline as instruments for *licensing* and *R&*D. The source of endogeneity, in this case, comes from unobserved factors that may drive both the firm value as well as the decision to invest in licensing agreements and R&D. The test for overidentifying restrictions is reported for all the GMM estimations and is significant in all my specifications. The *xtoverid* command in Stata 12 was used to test for overidentification (Schaffer and Stillman, 2006). The test statistic is distributed as chi-squared with degrees of freedom equal to the difference between the number of excluded instruments and the number of regressors. A rejection casts doubt on the validity of the instruments (Schaffer and Stillman, 2006).

Trademarks are often used to reinforce the appropriability of innovation returns (Fosfuri *et al.*, 2008). Therefore, trademarks could be associated with licensing and R&D investments as a mechanism to protect the innovative output. Firms can invest in trademarks to secure legal protection of their investments in marketing and complementary assets. The trademarks variable represents the cumulative number of trademarks assigned to firm *i*, and it is transformed using the natural logarithm. Data on trademarks was collected from the USPTO database. One limit of this instrument relates to the relation of intangible assets with market value: these assets account for a greater value of market capitalization, and this effect can change based on the organizational structure. Centralized firms should have more intangible assets because they are a key source of value creation, and they rely on internally generated knowledge. As a

consequence, there may be a difference in the level of intangible assets based on the organizational structure.[16]

Pharmaprojects contains independent ratings about the *novelty* of pharmaceutical compounds and the *speed* of development. For each compound in the pipeline, *novelty* is ranked on a 6-point scale in which higher values represent more innovative drugs. In Pharmaprojects, highly innovative compounds with unknown development strategies receive higher scores than drugs with established development strategies. In the case of novel drugs, firms should invest in R&D and licensing to boost their innovative production and reduce development uncertainty. I measured firm novelty as the natural logarithm of the percentage of drugs with the highest novelty rank (i.e., those with 6 points in the Pharmaprojects scale). On average, 17 % of the compounds in all development stages are highly innovative. A similar discussion can consider the development *speed* of pipeline compounds. Firms that invest in internal R&D and in external technology sources are able to increase the speed of development. Pharmaprojects includes a 4-point scale rating for the development speed of each compound in the pipeline. The instrumental variable is computed as the percentage of compounds with the highest development speed and transformed using the natural logarithm.

When a market is highly competitive, firms may have greater incentives to invest in innovative activities in order to develop new products and, potentially, gain a competitive advantage. I used the number of *competitors* in the same primary therapeutic area as a proxy for the incentive to be innovative and productive. Competition should

[16] It is possible to identify this difference in the data; in fact, centralized firms have 6 trademarks on average, whereas decentralized firms own only 3. The difference is significant at the 1% level.

trigger a more aggressive innovative behavior: firms may increase their investments in R&D and licensing to boost their productivity and introduce new products to protect or establish market leadership. The *competitors* variable was collected from the IMS database and it represents the number of companies with at least one product in the main therapeutic area of the focal firm. The variable is transformed using the natural logarithm.

Finally, I use the expected *market size* to proxy for exogenous drivers of the future demand of the firm. If the expected size of the market is large, firms have incentives to increase their innovative effort through R&D and licensing investments in order to develop a final product and appropriate the associated revenues (Acemoglu and Linn, 2004). Pharmaprojects includes estimates of the potential market size for compounds in development. I compute the expected market size for the focal firm by averaging the values of all the drugs in the pipeline in each year and then transforming it using the natural logarithm.

3.3.4. Controls

As proxy for the knowledge base of the company, I included the stock of patents assigned to the focal firm (*patent*). I included the number of employees to account for the effects related to the company size (*firm size*). The data was collected from Compustat. The firms in my sample employ a mean of approximately 15000 employees. Finally, I included specifications with time- trend dummies, *main therapeutic areas* (ATCs)[17] and firm-specific dummies to control for firm heterogeneity. In models without firm-fixed effects, I also included geographic-location dummies (*North America* and *Europe*).

[17] The *main therapeutic area* is defined as the ATC with the largest percentage of sales within the focal firm, and it varies over time.

Descriptive statistics and correlations are provided in Table 3.1 and in Table 3.2, respectively (both in Chapter 3 Appendix).

3.4. Results

The benchmark estimates to test my hypotheses are reported in Table 3.3. I use the natural logarithm of *market capitalization* at time *t-1* as dependent variable in all the specifications, while I use the 1-year lag for the independent variables transformed using the natural logarithm. Inward-looking behavior is measured by the percentage of backward self-citations. All models reported include year dummies and main therapeutic area ATC dummies. I use publication as a measure of absorptive capacity. All models are based on Equation (1), and they are estimated with three different methods: random effect, fixed effect and GMM with fixed effect. To test the first hypothesis, I compute the derivative with respect to *licensing* and *IOKA*, which is given by the coefficient of the interaction between these two variables. If firms show high levels of inward-looking behavior, they should suffer a negative bias toward external technologies; thus, I expect the sign of the marginal effect to be negative. As predicted, the interaction term between the *IOKA* and *licensing* investment variables has a negative sign across all specifications. The coefficient of the interaction term is statistically significant at the 5% and 10% level for the random effect and fixed effect models, respectively.

The combined effect of *IOKA* and *licensing* in Model 6 presents the same magnitude and sign as the other models; however, it is not statistically significant. The lack of significance in this specification may be attributed to weak instruments. The instruments pass the conventional test of overidentification (Hansen test), and the F-

statistic of the first stage is significant at the 5% level but below the conventional value of 10. The presence of weak instruments favors the rejection of the null hypothesis; therefore, the coefficients' result is not significant.

Table 3.3 Main results. Dependent variable Ln(1+MarketCapitalization)$_t$

	(1) RE	(2) RE	(3) FE	(4) FE	(5) GMM	(6) GMM
Licensing*IOKA		-0.558**		-0.543*		-0.538
		(0.222)		(0.313)		(0.624)
Licensing	0.034	0.082*	-0.004	0.037	-0.094	-0.278
	(0.038)	(0.042)	(0.045)	(0.046)	(0.169)	(0.204)
IOKA	0.922	3.152**	1.696	3.439**	3.474***	4.950***
	(1.270)	(1.409)	(1.571)	(1.341)	(0.932)	(1.873)
Decentralization	-0.308*	-0.267	-0.329	-0.273	-0.160	-0.092
	(0.178)	(0.171)	(0.220)	(0.214)	(0.199)	(0.218)
Patent	-0.058	-0.019	-0.103	-0.099	-0.138	-0.090
	(0.072)	(0.076)	(0.115)	(0.114)	(0.140)	(0.159)
Publication	0.101*	0.107*	-0.099	-0.082	-0.098*	-0.119**
	(0.057)	(0.055)	(0.083)	(0.081)	(0.053)	(0.059)
Firm Size	1.208***	1.217***	0.564*	0.679**	0.698	1.381*
	(0.123)	(0.120)	(0.286)	(0.297)	(0.540)	(0.704)
North America	-0.191	-0.141				
	(0.228)	(0.225)				
Europe	-0.143	-0.314				
	(0.479)	(0.482)				
Obs.	526	526	526	526	526	526
Num. Clusters	79	79	79	79	79	79
R-squared	0.823	0.825	0.365	0.466		
Hansen test					7.882	6.470
Hansen p-value					0.445	0.486

Clustered standard errors in parentheses, Stars represent the following significance levels: * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$ IOKA is defined as the percentage of backward self-citations.
Independent variables are at time t-1 and transformed using the natural logarithm, notation is omitted.
The F-stat of the first stage for Licensing is 2.377** for Models 5 and 6. The endogenous variables are instrumented using: Competitors, Market size, Novelty, Speed, Trademarks and their interactions with IOKA.

These results support the first hypothesis and confirm the substitute effect between inward-looking behavior and the adoption of external technologies. The magnitude of the coefficient represents a standard elasticity, suggesting that a 10% increase in both licensing investments and backward self-citations would yield a reduction in firm value of about 0.5%. In particular, the results in Table 3.3 suggest that when companies increasingly exploit internal knowledge, they may not be able to fully integrate acquired technologies. As a consequence, if firms consider their internal knowledge superior to external knowledge and adopt an inward-looking attitude, they may reject external technologies.

To test for the second and third hypotheses and understand the impact of organizational factors on the effect of inward-looking behavior, I re-estimate Equation (1) on different subsamples defined by the level of absorptive capacity and decentralization. The results are reported in Table 3.4 (in Chapter 3 Appendix). The first six models split the sample, based on the median value of the stock of publications. In particular, Models 1 to 3 are based on observations that are below the median value while Models 4 to 6 are estimated using observations above the median value. Similarly, Models 7 to 12 adopt subsamples based on the median value of decentralization. Models 7 to 9 are based on observations below the median, while Models 10 to 12 use the subsample with decentralization values above the median.

Consistent with my hypotheses, I find that the joint effect of IOKA and licensing is more evident in firms with low levels of absorptive capacity and firms that adopt a centralized organizational structure. For example, comparing the random effect models for the subsamples defined by the absorptive capacity variable (Model 1 and Model 4),

the difference between the coefficients of the interacted variable is negative.[18] Therefore, the difference between the two models suggests that firms with low levels of absorptive capacity experience more bias toward licensed technologies than firms with high levels of absorptive capacity.

The results are consistent across all models and support both my second and third hypotheses. Firms can use decentralization and absorptive capacity as mechanisms to moderate the negative bias introduced by inward-looking behavior. These results suggest that firms can mitigate the substitutability between IOKA and external technologies through higher levels of absorptive capacity or a decentralized organizational structure. The contribution of these results is twofold. First, results on absorptive capacity are in line with those of Rothaermel and Alexandre (2009): absorptive capacity allows firms to capture the benefits from different technology sources. Firms can engage in different innovative activities and minimize the negative attitude against external knowledge. Second, these results expand our understanding of decentralized organizational structure. They empirically test and expand the model introduced by Arora *et al.* (2013b) and demonstrate how licensing activity should be organized: in the case of decentralization, firms can profit from business units' superior information about external technologies and facilitate the integration with existing knowledge.

[18] For example, one can compare the random effect models with the split samples based on the level of absorptive capacity. The coefficient in Model 1 (low absorptive capacity) equals -1.279 and the coefficient in Model 4 (high absorptive capacity) is -0.274. The difference is -1.005, suggesting that the negative interaction between IOKA and licensing is more pronounced for firms with low levels of absorptive capacity.

3.5. Robustness analyses

3.5.1. Alternative measures of absorptive capacity

The results provided in Table 3.3 and Table 3.4 are robust to alternative estimation methods. Different estimates were used to verify this conclusion. All the methods adopted represent different ways to control for unobserved, firm-specific differences. The random effects model assumes that firm heterogeneity is random and uncorrelated with the explanatory variables, while the fixed effects model controls for unobserved heterogeneity by assuming that a firm fixed component is correlated with the explanatory variables. I also implemented an instrumental variable approach to help reduce endogeneity by using instruments that are uncorrelated with the error term.

To further validate the results, I adopt two alternative measures of absorptive capacity: the stock of R&D investments and the stock of scientific references. Table 3.5 replicates the benchmark regressions reported in Table 3.3: Models 1 to 3 use a dummy for absorptive capacity based on the stock of R&D, while Models 4 to 6 adopt the stock of scientific references as a measure of absorptive capacity.

The results confirm previous findings and support the first hypothesis. The magnitude of the estimated coefficients is also similar to those in Table 3.3, suggesting that a 10% increase in both *IOKA* and *licensing* reduces market capitalization by about 0.5%. The joint effect of *licensing* and *IOKA* is negative as predicted by H1, though it is insignificant for the GMM models. As mentioned in the previous section, the use of instruments that are statistically valid but with low explanatory power favors the rejection of the null hypothesis.

Table 3.5 Alternative measure of Absorptive capacity. Dependent variable Ln(1+MarketCapitalization)$_t$

	AC:R&D			AC: Scientific References		
	(1) RE	(2) FE	(3) GMM	(4) RE	(5) FE	(6) GMM
Licensing*IOKA	-0.554**	-0.543*	-0.522	-0.530**	-0.533*	-0.297
	(0.223)	(0.312)	(0.572)	(0.228)	(0.318)	(0.559)
Licensing	0.079*	0.036	-0.311	0.080*	0.036	-0.215
	(0.044)	(0.047)	(0.191)	(0.041)	(0.046)	(0.154)
IOKA	3.085**	3.427**	4.799***	2.917*	3.191**	4.212**
	(1.468)	(1.401)	(1.702)	(1.489)	(1.437)	(1.677)
AC	0.076	0.018	0.078	0.193	0.233	0.154
	(0.180)	(0.196)	(0.244)	(0.175)	(0.179)	(0.141)
Decentralization	-0.243	-0.267	-0.134	-0.244	-0.240	-0.174
	(0.174)	(0.218)	(0.198)	(0.176)	(0.221)	(0.187)
Patent	-0.019	-0.099	0.001	-0.066	-0.161	-0.066
	(0.075)	(0.115)	(0.158)	(0.076)	(0.114)	(0.137)
Publication	0.105*	-0.083	-0.224**	0.106**	-0.086	-0.173*
	(0.055)	(0.086)	(0.109)	(0.054)	(0.081)	(0.095)
Firm Size	1.208***	0.679**	1.537**	1.226***	0.708**	1.208**
	(0.117)	(0.296)	(0.607)	(0.119)	(0.295)	(0.527)
North America	-0.156			-0.121		
	(0.218)			(0.227)		
Europe	-0.323			-0.311		
	(0.482)			(0.489)		
Obs.	526	526	526	526	526	526
Num. Clusters	79	79	79	79	79	79
R-squared	0.826	0.467		0.825	0.458	
Hansen test			6.307			7.370
Hansen p-value			0.613			0.497

Clustered standard errors in parentheses, Stars represent the following significance levels: * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$. IOKA is defined as the percentage of backward self-citations.
Independent variables are at time t-1 and transformed using the natural logarithm, notation is omitted.
The F-stats of the first stage for Licensing are 2.625*** and 1.873* for models 3 and 6, respectively. The endogenous variables are instrumented using: Competitors, Market size, Novelty, Speed, Trademarks and their interactions with IOKA.

I test the robustness of the second and third hypotheses in Table 3.6a and Table 3.6b (in Chapter 3 Appendix). The former includes the stock of R&D as a measure of absorptive capacity, while the latter includes the stock of scientific references. Similarly

to Table 3.4, I present the benchmark regressions estimated on the split samples. The results show that the lack of absorptive capacity and the restrictions imposed by a centralized organizational structure emphasize the substitutability between internal knowledge and licensed technologies.

3.5.2. Alternative measures

The ratio of the stock of self-citations to the stock of patents as measures of *IOKA* is depicted in Tables 3.7 and 3.8 (in Chapter 3 Appendix). They replicate Equation (1) using the full sample and the split samples, respectively. Table 3.7 shows strong support for the first hypothesis. The exploitation of internal knowledge substitutes for the adoption of licensed technologies. Similar to other GMM estimations of Equation (1), the coefficients of the interacted variable in the GMM models are not significant, but they show the predicted negative sign and similar magnitude across all specifications.

My results on the second and third hypotheses are robust using the new measure of *IOKA.* As shown in Table 3.8, the coefficients of the interacted variable for the low absorptive capacity subsample models are significant and always smaller than the corresponding coefficients in the high absorptive capacity models. The same results are confirmed when I compare centralized and decentralized firms.

3.6. Discussion and conclusion

By analyzing licensing investment choices and R&D organizational structures, this paper contributes to a number of theoretical streams.

First, it has implications for the markets for technology literature, as it suggests that an IOKA process reduces the marginal effect of licensed technology on firms' market value. There exists a trade-off between the propensities to use internal knowledge and invest in external technologies. Despite the extensive literature on licensing transactions and the boundary of the firm, there is still a surprising lack of understanding about how firms are able to combine the licensed knowledge. It has been shown that companies can use external technologies to lower product development uncertainty (Danzon *et al.*, 2005), fill capability gaps (Agarwal and Helfat, 2009) and boost innovative production (Arora and Gambardella, 1990). However, firms may prefer the use of internal knowledge for several reasons: it facilitates the creation of norms and communication mechanisms, favors economies of scope, and rejects out-group knowledge (Cohen and Levinthal, 1990; Ingram and Simons, 2002; Parmigiani, 2007).

The results reported here expand our understanding of the relationship between the use of internal knowledge and the adoption of licensed technologies; in particular, the estimated coefficients suggest a substitute relationship. Companies that specialize in the use of their internal knowledge may experience a negative bias toward external technologies and, as a consequence, suffer from the NIH syndrome. As a result, the focus on internal knowledge may create a systematic bias toward external technology adoption. It follows that the reliance on internal knowledge has two contrasting effects. On one hand, companies can exploit social integration among employees to create a unique set of values, needs and beliefs, and consolidate internal knowledge flows to increase performance (Gioia *et al.*, 2000). In addition, firms can rely on their own knowledge to reinforce their capabilities, reduce their coordination costs and better manage their

internal innovative effort (Cohen and Levinthal, 1990). On the other hand, an inward-looking process may generate the NIH syndrome and introduce a negative attitude with respect to external knowledge, leading to an inefficient integration of acquired technologies (Agrawal *et al.*, 2010; Katz and Allen, 1982). Ultimately, this may reduce the firm's ability to implement an open-innovation strategy as well as the ability to rely on the market for technology.

Second, this paper contributes to the literature on centralization or decentralization of R&D and the allocation of resources (Argyres and Silverman, 2004; Arora *et al.*, 2013a; Arora *et al.*, 2013b). Centralized firms may suffer from a negative relationship because the licensing decision and the allocation of R&D resources are established by headquarters. The lack of participation by subsidiaries increases the likelihood of the rejection of external knowledge. In contrast, the results provide evidence that decentralized firms suffer less from inward-looking behavior. I find that their organizational structure affects the relation between internal and external knowledge and reduces the negative bias toward external technologies. Overall, decentralization allows for the exploitation of private information held by R&D units and facilitates a less hostile environment toward external technologies. These results are in line with the idea promoted by Williamson (1985), that decentralization enhances the incentives of unit managers and favors a better information flow within the organization.

Third, this paper confirms the role of absorptive capacity as a moderating variable that can reduce the negative bias toward external technologies. The integration of external knowledge is determined by the level of absorptive capacity possessed by the focal firm. A firm's knowledge base reduces the uncertainty around external

technologies, which allows firms to better select them. Firms can use their knowledge base to create bridges across knowledge sources (Reagans and McEvily, 2003; Rothaermel and Alexandre, 2009).

Although this study has some limitations, it offers potential areas for future research. First, the reported results do not identify the underlying mechanisms by which internal knowledge generates inward-looking behavior. Thus, it is important to specify that the empirical regressions do not establish any direction of causality; rather, they express the conditional correlations between my measures. Future research should explore the identification of the development of the IOKA process, and link its impact on novel organizational factors. Second, though the instrumental variables are valid as reported by the Hansen test of overidentification, their explanatory power may be weak. While the F-statistics of the first stage regressions are significant, at least at the 10% level, they are below the conventional value of 10. Therefore, the GMM estimations may suffer from biased standard errors that lead to a rejection of the null hypothesis too often. However, it is crucial to point out that the sign and magnitude of the GMM coefficients are similar to other estimation methods and are in line with my hypotheses. Third, by only analyzing the pharmaceutical industry, I may limit the generalization of these results to other industries; therefore, a deeper analysis into other industries is necessary to fully understand the impact of inward-looking behavior and its conditioning factors.

Finally, from a practical point of view, this study has important managerial implications. This paper shows the importance of managing knowledge within organizational boundaries and the role played by organizational structure in adopting and internalizing external technologies. Firms often favor the exploitation of internal

knowledge to reduce their costs and to specialize on technological trajectories; however, the same attitude may limit the ability to integrate external knowledge that may help with market value. In addition, managers should be aware that the make-versus-buy decision should account for organizational characteristics such as the decentralization level and existing knowledge base.

CHAPTER 3 APPENDIX

Table 3.1 Descriptive Statistics

Variable	Mean	Std. Dev.	Min	Max
Market capitalization	20,709.200	41,705.130	1.024	290,444
Licensing stock	12,556.830	58,964.940	0	935,353
% Self-citation	0.081	0.128	0	1
Self-citation Stock/Patent Stock	0.427	0.569	0	3.408
R&D Stock	2,867.351	8,005.418	0	76,857
Publication Stock	647.189	1,775.481	0	16,645
Scientific references Stock	531.549	1,489.949	0	13,633
Decentralization	0.442	0.455	0	1
Competitors	1,262.472	571.965	191	2,701
Market size	7,070,323	12,500,000	0	104,000,000
Speed	0.065	0.145	0	1
Novelty	0.173	0.304	0	1
Trademarks stock	17.235	60.623	0	832
Patent stock	86.839	232.096	0	2,121
Firm size (thousands)	15.408	28.618	0	138
North America	0.847	0.360	0	1
Europe	0.120	0.325	0	1

All financial variables are presented in year 2000 constant U.S. dollars

Table 3.2 Correlation Table

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1.Market capitalization	1																
2.Licensing stock	0.471	1															
3.% Self-citation	0.126	0.054	1														
4.Self-citation /Patent	-0.006	-0.043	0.735	1													
5.R&D Stock	0.740	0.786	0.065	-0.022	1												
6.Publication Stock	0.652	0.555	0.053	-0.049	0.815	1											
7.Scientific references Stock	0.558	0.552	0.326	0.120	0.659	0.609	1										
8.Decentralization	0.055	0.112	-0.203	-0.139	0.099	0.130	-0.006	1									
9.Competitors	0.160	0.178	0.031	-0.118	0.245	0.234	0.190	0.020	1								
10.Market size	0.119	0.010	-0.034	0.001	0.061	-0.006	0.036	0.063	0.091	1							
11.Speed	-0.043	0.019	0.189	0.025	0.014	-0.011	-0.042	0.037	0.132	-0.106	1						
12.Novelty	0.163	0.150	0.313	0.060	0.160	0.156	0.151	-0.046	0.028	-0.125	0.250	1					
13.Trademarks stock	0.485	0.392	-0.002	0.003	0.663	0.677	0.309	-0.017	0.115	0.067	0.001	0.056	1				
14.Patent stock	0.579	0.582	0.319	0.115	0.687	0.609	0.995	-0.028	0.198	0.037	-0.045	0.152	0.332	1			
15.Firm size (thousands)	0.883	0.499	0.108	0.034	0.743	0.650	0.542	0.034	0.180	0.140	-0.005	0.082	0.503	0.568	1		
16.North America	-0.133	-0.258	0.160	0.134	-0.144	-0.097	-0.009	-0.134	-0.314	0.026	-0.019	-0.245	-0.060	-0.028	-0.173	1	
17.Europe	0.191	0.317	-0.160	-0.136	0.203	0.146	0.041	0.177	0.268	-0.003	0.024	0.184	0.096	0.057	0.233	-0.872	1

Table 3.4 Split sample regressions. Dependent variable Ln(1+MarketCapitalization)$_t$

	Low AC			High AC			Centralized			Decentralized		
	RE	FE	GMM	RE	FE	GMM	RE	FE	GMM	RE	FE	GMM
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Licensing*IOKA	-1.716***	-1.740**	-1.601*	-0.359	-0.302	0.424	-0.818**	-1.228***	-1.685**	-0.624***	-0.571**	0.575
	(0.330)	(0.788)	(0.885)	(0.318)	(0.371)	(0.507)	(0.358)	(0.414)	(0.683)	(0.218)	(0.247)	(0.484)
Licensing	0.175***	0.045	0.016	0.094	0.055	-0.272	0.125	0.121	-0.176	0.090**	0.040	0.396**
	(0.051)	(0.050)	(0.094)	(0.066)	(0.073)	(0.232)	(0.081)	(0.101)	(0.210)	(0.038)	(0.041)	(0.186)
IOKA	5.070***	4.945***	5.234***	2.855	3.409	1.067	1.838	1.489	5.125**	4.092***	4.517***	-0.024
	(1.554)	(1.350)	(1.385)	(1.968)	(2.047)	(2.217)	(2.276)	(1.612)	(2.070)	(1.581)	(1.387)	(1.899)
Decentralization	0.787***	0.537	0.657***	-0.434**	-0.497*	-0.387	-0.401	-0.186	-0.064	0.410	0.323	0.346
	(0.303)	(0.377)	(0.245)	(0.215)	(0.252)	(0.255)	(0.338)	(0.314)	(0.306)	(0.300)	(0.316)	(0.387)
Patent	0.093	-0.008	0.045	0.004	-0.009	0.019	0.201*	0.253	0.537*	-0.138	-0.376**	-0.34***
	(0.138)	(0.212)	(0.150)	(0.070)	(0.136)	(0.125)	(0.106)	(0.220)	(0.298)	(0.090)	(0.162)	(0.119)
Publication	0.248***	-0.103	0.005	0.119*	-0.076	-0.045	0.150	-0.598**	-0.332	0.122*	0.046	0.044
	(0.086)	(0.216)	(0.156)	(0.068)	(0.098)	(0.080)	(0.094)	(0.281)	(0.226)	(0.071)	(0.124)	(0.077)
Firm Size	1.210***	-0.401	-0.038	1.054***	0.722**	1.159	0.993***	0.209	1.235*	1.259***	0.435	-0.584
	(0.181)	(0.760)	(0.575)	(0.125)	(0.287)	(0.710)	(0.191)	(0.347)	(0.656)	(0.119)	(0.443)	(0.726)
North America	0.251			-0.303			0.336			-0.359*		
	(0.292)			(0.378)			(0.597)			(0.217)		
Europe	0.701			-0.070			0.005			-0.212		
	(0.876)			(0.486)			(0.667)			(0.467)		
Obs.	302	302	302	371	371	371	287	287	287	386	386	386
Num. Clusters	55	55	55	58	58	58	51	51	51	72	72	72
R-Squared	.808311	.057783		.798695	.558376		.770655	.151869		.88384	.296386	
Hansen test			9.367			7.154			6.873			5.052
Hansen p-value			0.227			0.307			0.442			0.654

Clustered standard errors in parentheses, Stars represent the following significance levels: * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

IOKA is defined as the percentage of backward self-citations.

Independent variables are at time t-1 and transformed using the natural logarithm, notation is omitted.

The F-stats of the first stage for Licensing are 2.957***, 2.838***, 2.830*** and 1.130 for Models 3, 6, 9 and 12, respectively. The endogenous variables are instrumented using: Competitors, Market size, Novelty, Speed, Trademarks and their interactions with IOKA.

Table 3.6a Split sample regressions with R&D Stock as Absorptive Capacity. Dependent variable Ln(1+MarketCapitalization)$_t$

	Low AC			High AC			Centralized			Decentralized		
	RE	FE	GMM	RE	FE	GMM	RE	FE	GMM	RE	FE	GMM
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Licensing*IOKA	-1.090***	-0.707	0.537	0.014	0.025	0.458	-0.910**	-1.503***	-2.196***	-0.399**	-0.385	-0.155
	(0.327)	(0.541)	(1.109)	(0.038)	(0.039)	(0.746)	(0.375)	(0.475)	(0.636)	(0.203)	(0.242)	(0.514)
Licensing	0.098**	0.054	0.058	-1.067	-0.223	0.049	0.154*	0.183*	-0.167	0.045*	0.008	-0.074
	(0.038)	(0.045)	(0.176)	(1.520)	(1.627)	(0.236)	(0.086)	(0.102)	(0.191)	(0.027)	(0.028)	(0.175)
IOKA	2.316**	2.152*	0.142	-0.057	-0.041	-2.061	2.374	1.463	5.444***	3.736***	3.987***	2.283
	(1.080)	(1.110)	(1.464)	(0.147)	(0.150)	(4.060)	(2.538)	(1.787)	(1.810)	(1.264)	(1.321)	(1.418)
R&D Stock	.	.	.	.	.	.	0.003	-0.089	-0.049	0.048	0.044	0.054
							(0.275)	(0.250)	(0.271)	(0.174)	(0.154)	(0.167)
Decentralization	-0.007	-0.011	-0.107	-0.057	-0.041	-0.049	.	.	.	.	.	.
	(0.133)	(0.142)	(0.170)	(0.147)	(0.150)	(0.102)						
Patent	0.233**	0.418**	0.459***	-0.046	-0.120**	-0.154*	0.246**	0.317	0.595**	-0.078	-0.086	-0.062
	(0.118)	(0.208)	(0.173)	(0.057)	(0.057)	(0.086)	(0.107)	(0.234)	(0.273)	(0.074)	(0.083)	(0.087)
Publication	0.049	-0.062	0.005	0.077	-0.024	-0.026	0.236***	-0.485	-0.297	0.096	0.031	0.017
	(0.080)	(0.171)	(0.160)	(0.055)	(0.041)	(0.085)	(0.089)	(0.293)	(0.256)	(0.060)	(0.062)	(0.095)
Firm Size	1.274***	0.616	0.198	0.977***	0.387**	0.150	0.899***	0.227	1.027*	1.176***	0.404**	0.320
	(0.199)	(0.433)	(0.557)	(0.093)	(0.183)	(0.524)	(0.174)	(0.267)	(0.543)	(0.109)	(0.155)	(0.215)
North America	-0.131			0.335			0.482			-0.239		
	(0.376)			(0.605)			(0.492)			(0.201)		
Europe	0.397			0.659			-0.349			0.272		
	(0.559)			(0.644)			(0.527)			(0.308)		
Obs.	283	283	272	390	390	386	237	237	227	436	436	428
Num. Clusters	64	64	53	58	58	54	51	51	41	78	78	70
R-Squared	0.645	0.326		0.767	0.305		0.831	0.061		0.839	0.602	
Hansen test			9.512			6.440			5.811			5.746
Hansen p-value			0.218			0.376			0.562			0.570

Clustered standard errors in parentheses, Stars represent the following significance levels: * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

IOKA is defined as the percentage of backward self-citations.

Independent variables are at time t-1 and transformed using the natural logarithm, notation is omitted.

The F-stats of the first stage for Licensing are 4.279***, 3.342***, 2.354*** and 0.921 for Models 3, 6, 9 and 12, respectively. The endogenous variables are instrumented using: Competitors, Market size, Novelty, Speed, Trademarks and their interactions with IOKA.

"." means the corresponding variable was dropped from estimation because of collinearity. The collinearity occurred because in the estimation I used the dummy form of R&D Stock (1 if is above the sample median, and 0 if otherwise). When I use the continuous form of R&D Stock, the results remain qualitatively unchanged.

Table 3.6b Split sample regressions with Scientific References Stock as Absorptive Capacity. Dependent variable Ln(1+MarketCapitalization)$_t$

	Low AC			High AC			Centralized			Decentralized		
	RE	FE	GMM	RE	FE	GMM	RE	FE	GMM	RE	FE	GMM
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Licensing*IOKA	-0.713*	-0.496	0.765	-0.426	-0.435	-0.208	-0.816**	-1.396***	-1.614**	-0.397*	-0.375	-0.212
	(0.386)	(0.610)	(0.502)	(0.322)	(0.409)	(0.558)	(0.400)	(0.468)	(0.639)	(0.208)	(0.242)	(0.521)
Licensing	0.070**	0.028	0.066	0.079	0.058	-0.081	0.141	0.163	-0.340**	0.045*	0.007	-0.094
	(0.031)	(0.038)	(0.142)	(0.066)	(0.077)	(0.250)	(0.086)	(0.107)	(0.168)	(0.026)	(0.028)	(0.182)
IOKA	1.609	0.907	0.334	3.424*	4.195**	2.968	1.868	0.881	3.040	3.786***	4.031***	2.402
	(1.517)	(1.434)	(0.805)	(1.796)	(1.871)	(2.359)	(2.631)	(1.876)	(2.058)	(1.314)	(1.367)	(1.465)
Scientific References Stock							0.316	0.342	0.627***	-0.036	-0.082	-0.135
							(0.319)	(0.309)	(0.227)	(0.180)	(0.165)	(0.162)
Decentralization	0.042	0.080	0.010	-0.152	-0.170	-0.100						
	(0.130)	(0.136)	(0.130)	(0.159)	(0.161)	(0.105)						
Patent	0.302*	0.359*	0.449**	-0.069	-0.126	-0.088	0.165	0.220	0.543**	-0.074	-0.072	-0.022
	(0.174)	(0.184)	(0.203)	(0.064)	(0.096)	(0.167)	(0.123)	(0.239)	(0.243)	(0.084)	(0.089)	(0.095)
Publication	0.121*	0.013	0.020	0.137*	-0.017	-0.053	0.227***	-0.516**	-0.521**	0.096	0.030	0.012
	(0.072)	(0.129)	(0.128)	(0.074)	(0.079)	(0.046)	(0.084)	(0.253)	(0.219)	(0.060)	(0.061)	(0.096)
Firm Size	1.137***	0.281	0.244	1.129***	0.600**	0.626	0.940***	0.363	1.269***	1.185***	0.412**	0.365
	(0.130)	(0.172)	(0.174)	(0.121)	(0.288)	(0.815)	(0.183)	(0.291)	(0.483)	(0.104)	(0.162)	(0.246)
North America	-0.284			0.046			0.549			-0.248		
	(0.285)			(0.331)			(0.546)			(0.203)		
Europe	0.607			-0.098			-0.265			0.269		
	(0.459)			(0.590)			(0.554)			(0.312)		
Obs.	319	319	319	354	354	354	237	237	237	436	436	436
Num. Clusters	57	57	57	57	57	57	51	51	51	78	78	78
R-Squared	0.685	0.116		0.805	0.326		0.830	0.030		0.839	0.597	
Hansen test			7.971			4.276			6.551			5.721
Hansen p-value			0.335			0.639			0.477			0.573

Clustered standard errors in parentheses, Stars represent the following significance levels: * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

IOKA is defined as the percentage of backward self-citations. Independent variables are at time t-1 and transformed using the natural logarithm, notation is omitted.

The F-stats of the first stage for Licensing are 3.793***, 1.26, 5.043*** and 0.838 for Models 3, 6, 9 and 12, respectively. The endogenous variables are instrumented using: Competitors, Market size, Novelty, Speed, Trademarks and their interactions with IOKA. "." means the corresponding variable was dropped from estimation because of collinearity. The collinearity occurred because I used the dummy form of Scientific References Stock. When I use the continuous form, the results remain qualitatively unchanged.

Table 3.7 Robustness Regressions with IOKA defined as the stock of backward self-citations divided by the stock of patents. Dependent variable Ln(1+MarketCapitalization)$_t$

	AC: Publication Stock			AC: R&D Stock			AC: Scientific References Stock		
	(1) RE	(2) FE	(3) GMM	(4) RE	(5) FE	(6) GMM	(7) RE	(8) FE	(9) GMM
Licensing*IOKA	-0.12***	-0.122**	-0.090	-0.12***	-0.121**	-0.089	-0.11***	-0.122**	-0.068
	(0.043)	(0.052)	(0.093)	(0.044)	(0.053)	(0.095)	(0.045)	(0.054)	(0.088)
Licensing	0.103**	0.062	-0.318*	0.101**	0.063	-0.308*	0.102**	0.062	-0.226
	(0.046)	(0.048)	(0.182)	(0.049)	(0.051)	(0.171)	(0.045)	(0.047)	(0.172)
IOKA	0.751***	0.983***	0.836**	0.744***	0.993***	0.835**	0.717***	0.941***	0.788**
	(0.257)	(0.288)	(0.334)	(0.269)	(0.299)	(0.330)	(0.263)	(0.294)	(0.312)
AC				0.045	-0.028	0.048	0.199	0.229	0.166
				(0.171)	(0.180)	(0.220)	(0.162)	(0.161)	(0.136)
Decentralization	-0.206	-0.188	-0.078	-0.197	-0.203	-0.093	-0.186	-0.161	-0.107
	(0.184)	(0.229)	(0.194)	(0.174)	(0.213)	(0.193)	(0.179)	(0.221)	(0.190)
Patent	-0.018	-0.080	0.032	-0.018	-0.080	0.034	-0.065	-0.141	-0.042
	(0.072)	(0.112)	(0.158)	(0.072)	(0.111)	(0.158)	(0.079)	(0.113)	(0.136)
Publication	0.101	-0.095	-0.207*	0.103*	-0.089	-0.200*	0.102*	-0.095	-0.158
	(0.074)	(0.115)	(0.120)	(0.059)	(0.100)	(0.104)	(0.057)	(0.094)	(0.100)
Firm Size	1.179***	0.607**	1.344**	1.175***	0.608**	1.354***	1.191***	0.640**	1.119**
	(0.130)	(0.263)	(0.533)	(0.127)	(0.264)	(0.509)	(0.129)	(0.261)	(0.493)
North America	-0.114			-0.121			-0.092		
	(0.242)			(0.245)			(0.246)		
Europe	-0.232			-0.234			-0.235		
	(0.515)			(0.518)			(0.525)		
Obs.	526	526	526	526	526	526	526	526	526
Num. Clusters	79	79	79	79	79	79	79	79	79
R-squared	0.820	0.429		0.820	0.431		0.819	0.423	
Hansen test			6.544			6.617			7.410
Hansen p-value			0.587			0.579			0.493

Clustered standard errors in parentheses, Stars represent the following significance levels: * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$
IOKA is defined as the stock of backward self-citations divided by the stock of patents.
Independent variables are at time t-1 and transformed using the natural logarithm, notation is omitted.
The F-stats of the first stage for Licensing are 2.031**, 2.484**, 1.731* for Models 3, 6 and 9 respectively. The endogenous variables are instrumented using: Competitors, Market size, Novelty, Speed, Trademarks and their interactions with IOKA.
The variable AC is the dummy form of R&D Stock and Scientific References Stock (1 if is above the sample median, and 0 if otherwise) for Models 4 to 6 and Models 7 to 9, respectively. When I use the continuous form of Scientific References Stock, the results remain qualitatively unchanged.

Table 3.8a Split sample regressions with Publication Stock as Absorptive Capacity and IOKA as the stock of backward self-citations divided by the stock of patents. Dependent variable Ln(1+MarketCapitalization)$_t$

	Low AC			High AC			Centralized			Decentralized		
	RE	FE	GMM	RE	FE	GMM	RE	FE	GMM	RE	FE	GMM
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Licensing*IOKA	-0.242**	-0.192*	-0.186	-0.042	-0.076	0.067	-0.144**	-0.26***	-0.34**	-0.084*	-0.129**	-0.079
	(0.095)	(0.108)	(0.149)	(0.046)	(0.050)	(0.062)	(0.063)	(0.082)	(0.147)	(0.047)	(0.051)	(0.110)
Licensing	0.083**	0.063*	0.072	0.067	0.067	-0.029	0.155*	0.167	-0.211	0.059**	0.034	-0.017
	(0.033)	(0.038)	(0.115)	(0.054)	(0.056)	(0.115)	(0.082)	(0.104)	(0.163)	(0.027)	(0.029)	(0.142)
IOKA	0.738**	1.147***	0.940**	0.343	0.557	0.271	0.564	0.294	0.371	0.892***	1.241***	0.833*
	(0.308)	(0.362)	(0.454)	(0.314)	(0.349)	(0.315)	(0.361)	(0.365)	(0.362)	(0.269)	(0.313)	(0.449)
Publication	.	.	.	.	.	.	0.097	0.135	0.310	-0.198	-0.091	-0.062
							(0.340)	(0.303)	(0.203)	(0.179)	(0.152)	(0.155)
Decentralization	0.320	0.262	0.176	-0.175*	-0.144	-0.18**	.	.	.	.	.	.
	(0.223)	(0.247)	(0.183)	(0.091)	(0.097)	(0.070)						
Patent	0.142	0.276*	0.338***	-0.077	-0.126	-0.118	0.174*	0.225	0.762**	-0.103	-0.107	-0.085
	(0.122)	(0.163)	(0.126)	(0.076)	(0.113)	(0.081)	(0.105)	(0.242)	(0.302)	(0.072)	(0.075)	(0.071)
Firm Size	1.100***	0.182	0.177	1.091***	0.625***	0.550	0.892***	0.188	0.784	1.166***	0.443***	0.396**
	(0.172)	(0.269)	(0.220)	(0.106)	(0.230)	(0.345)	(0.190)	(0.234)	(0.537)	(0.105)	(0.158)	(0.198)
North America	-0.202			-0.299			0.213			-0.040		
	(0.340)			(0.285)			(0.434)			(0.240)		
Europe	1.049			0.014			-0.390			0.582*		
	(0.714)			(0.359)			(0.548)			(0.342)		
Obs.	302	302	302	371	371	371	237	237	237	436	436	436
Num. Clusters	55	55	55	58	58	58	51	51	51	78	78	78
R-Squared	0.692	0.145		0.779	0.485		0.848	0.211		0.833	0.536	
Hansen test			6.442			4.182			7.674			5.861
Hansen p-value			0.489			0.652			0.362			0.556

Clustered standard errors in parentheses, Stars represent the following significance levels: * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

IOKA is defined as the stock of backward self-citations divided by the stock of patents.

Independent variables are at time t-1 and transformed using the natural logarithm, notation is omitted.

The F-stats of the first stage for Licensing are 3.258***, 5.763***, 3.025*** and 1.031 for Models 3, 6, 9 and 12, respectively. The endogenous variables are instrumented using: Competitors, Market size, Novelty, Speed, Trademarks and their interactions with IOKA.

"." means the corresponding variable was dropped from estimation because of collinearity. The collinearity occurred because in the estimation I used the dummy form of Publication Stock (1 if is above the sample median, and 0 if otherwise). When I use the continuous form of Publication Stock, the results remain qualitatively unchanged.

Table 3.8b Split sample regressions with R&D Stock as Absorptive Capacity and IOKA as the stock of backward self-citations divided by the stock of patents. Dependent variable Ln(1+MarketCapitalization)$_t$

	Low AC			High AC			Centralized			Decentralized		
	RE	FE	GMM	RE	FE	GMM	RE	FE	GMM	RE	FE	GMM
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Licensing*IOKA	-0.216**	-0.178*	0.398	0.025	-0.001	0.119*	-0.167**	-0.26***	-0.45***	-0.090*	-0.133**	-0.084
	(0.090)	(0.092)	(0.270)	(0.035)	(0.036)	(0.067)	(0.069)	(0.093)	(0.169)	(0.047)	(0.052)	(0.113)
Licensing	0.096**	0.065	0.186	0.013	0.027	0.085	0.157	0.171	-0.329*	0.057**	0.033	-0.006
	(0.040)	(0.044)	(0.209)	(0.035)	(0.035)	(0.118)	(0.098)	(0.110)	(0.194)	(0.028)	(0.029)	(0.135)
IOKA	0.433	0.565	-0.509	-0.139	0.090	-0.267	0.595	0.317	0.307	0.857***	1.224***	0.832*
	(0.341)	(0.395)	(0.405)	(0.284)	(0.309)	(0.374)	(0.405)	(0.421)	(0.423)	(0.272)	(0.315)	(0.446)
R&D Stock	.	.	.	.	.	.	-0.045	-0.079	-0.141	0.053	0.064	0.108
							(0.309)	(0.322)	(0.287)	(0.170)	(0.146)	(0.149)
Decentralization	0.015	0.020	-0.397*	-0.059	-0.040	-0.023	.	.	.	.	.	.
	(0.145)	(0.143)	(0.218)	(0.148)	(0.151)	(0.093)						
Patent	0.245*	0.397*	0.519***	-0.049	-0.12**	-0.16**	0.213**	0.234	0.959***	-0.095	-0.102	-0.086
	(0.131)	(0.216)	(0.195)	(0.062)	(0.060)	(0.071)	(0.106)	(0.243)	(0.326)	(0.073)	(0.080)	(0.073)
Publication	0.041	-0.062	0.073	0.075	-0.029	-0.015	0.213**	-0.583	-0.506*	0.097	0.029	0.013
	(0.080)	(0.169)	(0.199)	(0.054)	(0.040)	(0.049)	(0.097)	(0.409)	(0.286)	(0.060)	(0.062)	(0.067)
Firm Size	1.255***	0.544	0.203	0.980***	0.377**	0.043	0.891***	0.155	0.918	1.147***	0.416***	0.344*
	(0.211)	(0.395)	(0.749)	(0.095)	(0.177)	(0.262)	(0.199)	(0.240)	(0.565)	(0.110)	(0.153)	(0.182)
North America	-0.081			0.343			0.322			-0.110		
	(0.402)			(0.605)			(0.482)			(0.245)		
Europe	0.521			0.671			-0.386			0.491		
	(0.553)			(0.652)			(0.621)			(0.333)		
Obs.	283	283	283	390	390	390	237	237	237	436	436	436
Num. Clusters	64	64	64	58	58	58	51	51	51	78	78	78
R-Squared	0.638	0.290		0.766	0.285		0.835	0.208		0.833	0.548	
Hansen test			6.224			3.224			5.608			5.828
Hansen p-value			0.514			0.780			0.586			0.560

Clustered standard errors in parentheses, Stars represent the following significance levels: * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

IOKA is defined as the stock of backward self-citations divided by the stock of patents.

Independent variables are at time t-1 and transformed using the natural logarithm, notation is omitted.

The F-stats of the first stage for Licensing are 2.167**, 4.449***, 2.353** and 1.072 for Models 3, 6, 9 and 12, respectively. The endogenous variables are instrumented using: Competitors, Market size, Novelty, Speed, Trademarks and their interactions with IOKA.

"." means the corresponding variable was dropped from estimation because of collinearity. The collinearity occurred because in the estimation I used the dummy form of R&D Stock (1 if is above the sample median, and 0 if otherwise). When I use the continuous form of R&D Stock, the results remain qualitatively unchanged.

Table 3.8c Split sample regressions with Scientific References Stock as Absorptive Capacity and IOKA as the stock of backward self-citations divided by the stock of patents. Dependent variable Ln(1+MarketCapitalization)$_t$

	Low AC			High AC			Centralized			Decentralized		
	RE	FE	GMM	RE	FE	GMM	RE	FE	GMM	RE	FE	GMM
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Licensing*IOKA	-0.120	0.148	0.229	-0.097	-0.15**	0.152*	-0.155**	-0.25***	-0.334**	-0.089*	-0.131**	-0.090
	(0.095)	(0.098)	(0.336)	(0.067)	(0.073)	(0.088)	(0.068)	(0.079)	(0.153)	(0.047)	(0.051)	(0.110)
Licensing	0.073**	0.034	0.288	0.103	0.120*	-0.003	0.144	0.157	-0.38***	0.058**	0.032	-0.018
	(0.032)	(0.039)	(0.180)	(0.072)	(0.071)	(0.176)	(0.091)	(0.104)	(0.140)	(0.027)	(0.029)	(0.145)
IOKA	0.647*	0.451	0.442	0.595	1.095**	0.004	0.500	0.207	-0.032	0.873***	1.238***	0.856*
	(0.373)	(0.397)	(0.579)	(0.427)	(0.450)	(0.405)	(0.382)	(0.391)	(0.326)	(0.279)	(0.321)	(0.442)
Scientific References	.	.	.	.	.	.	0.352	0.396	0.816***	-0.062	-0.099	-0.119
							(0.297)	(0.304)	(0.211)	(0.173)	(0.159)	(0.148)
Decentralization	0.072	0.082	0.110	-0.155	-0.185	-0.170	.	.	.	.	.	.
	(0.126)	(0.144)	(0.137)	(0.156)	(0.160)	(0.123)						
Patent	0.246	0.291	0.450**	-0.059	-0.145	-0.128	0.130	0.124	0.617**	-0.087	-0.087	-0.054
	(0.180)	(0.185)	(0.186)	(0.073)	(0.091)	(0.115)	(0.129)	(0.257)	(0.265)	(0.080)	(0.082)	(0.079)
Publication	0.108	0.014	-0.098	0.151**	-0.007	-0.043	0.199**	-0.611*	-0.71***	0.097	0.028	0.006
	(0.072)	(0.124)	(0.133)	(0.077)	(0.081)	(0.042)	(0.086)	(0.324)	(0.243)	(0.060)	(0.061)	(0.069)
Firm Size	1.124***	0.295*	0.117	1.102***	0.501*	0.126	0.940***	0.321	1.143**	1.156***	0.429***	0.392*
	(0.125)	(0.173)	(0.185)	(0.127)	(0.270)	(0.473)	(0.208)	(0.249)	(0.463)	(0.106)	(0.159)	(0.211)
North America	-0.165			0.038			0.411			-0.117		
	(0.299)			(0.350)			(0.529)			(0.249)		
Europe	0.823*			-0.135			-0.301			0.496		
	(0.427)			(0.621)			(0.633)			(0.340)		
Obs.	319	319	315	354	354	347	237	237	227	436	436	428
Num. Clusters	57	57	53	57	57	50	51	51	41	78	78	70
R-Squared	0.680	0.089		0.793	0.224		0.833	0.137		0.832	0.543	
Hansen test			12.900			3.266			6.383			5.966
Hansen p-value			0.075			0.659			0.496			0.544

Clustered standard errors in parentheses, Stars represent the following significance levels: * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

IOKA is defined as the stock of backward self-citations divided by the stock of patents.

Independent variables are at time t-1 and transformed using the natural logarithm, notation is omitted.

The F-stats of the first stage for Licensing are 3.398***, 1.773, 2.972*** and 0.937 for Models 3, 6, 9 and 12, respectively. The endogenous variables are instrumented using: Competitors, Market size, Novelty, Speed, Trademarks and their interactions with IOKA.

"." means the corresponding variable was dropped from estimation because of collinearity. The collinearity occurred because in the estimation I used the dummy form of Scientific References Stock (1 if is above the sample median, and 0 if otherwise). When I use the continuous form of Scientific References Stock, the results remain qualitatively unchanged.

CHAPTER 4

HOW RELIABLE IS THE MARKET FOR TECHNOLOGY?

4.1. Introduction

The development of new technologies has become a process that involves multiple firms in multiple stages (Arora *et al.*, 2001). According to the market for technology literature, firms can boost their innovative performance by combining different technological inputs acquired through several mechanisms such as licensing and acquisitions. Research on this topic has mostly focused on the supply of technology to the market, although a few recent papers have studied the role of the demand side (Arora *et al.*, 2001; Cassiman and Veugelers, 2006; Laursen and Salter, 2006) by focusing on the effect of external technologies on firm performance. However, in the context of interfirm collaboration, the importance of intellectual property management and the role of acquired patents in case of litigation have been greatly overlooked. In particular, existing research has disregarded the significance and the reliance of acquired technologies after a final innovation is commercialized. We aim to reduce this gap by analyzing the strength of acquired patents when challenged in court litigations. This research helps increase our understanding of the role of the markets for technology and the ability of acquired patents to protect the stability of downstream revenues.

The ability to manage intellectual property rights is increasingly becoming an important aspect of corporate strategy, and this effect is emphasized for technological firms that exploit patents to gain competitive advantage (Rivette and Kline, 2000). Patents are an important factor to protect and stimulate innovative research as well as its development, and this is even more significant in the pharmaceutical industry than in

other sectors (Cohen *et al.*, 2000; Levin *et al.*, 1987). As such, firms can exploit technology acquisitions to boost productivity, but once a downstream product is commercialized, its protection is limited by the uncertainty of patent litigations. Patents grant the right to exclude someone from commercializing an invention; this privilege is conditional, however, on the uncertainty related to litigation outcomes (Lemley and Shapiro, 2005).

We argue that, in case of litigation, patents acquired through the markets for technology may differ from those developed internally for various reasons. First, technology buyers investigate the quality of the acquired technology through the due diligence procedure and select the best technologies available on the market. This selection process should favor the acquisition of patents that are better than those developed internally because internal patents are not screened through the due diligence procedure. Second, companies that specialize as technology suppliers may have superior legal capabilities to provide higher quality patents, thereby increasing the quality of the supplied technology. However, the counterargument may be true as well; for example, it is possible that external patents are developed by a technology supplier with inferior legal capabilities (e.g., small companies with inferior capabilities), thus increasing the chances of a lower quality patent. As a result, uncertainty still exists as to whether acquired patents are able to protect future revenues in case of litigation and whether they differ from technologies produced within the firm's boundaries.

If we combine the idea of litigation uncertainty with the fact that firms pay a patent premium to increase the value of their innovation (Arora *et al.*, 2008), it is strategically important to understand the differences between acquired and internally

developed patents. In particular, the level of protection may differ between internal and external patents to such a degree that it may increase or decrease the probability of winning patent litigations and, in turn, the stability of the incumbent revenues. The consequences of patent litigation are important since the profitability of a product is limited by the potential entry of other competitors. If the litigation is not successful and patents are not reliable, patent holders can suffer from significant revenue losses. Due to the uncertainty that characterizes the development process and the substantial investments required, patents are an essential factor to recover R&D expenditures through future revenues (Cohen *et al.*, 2000). It follows that if external patents are less reliable than internal ones, investments in external technologies may undermine future revenues and, as a result, generate negative profits that reduce the incentives to innovate.

Our research contributes to both the markets for technology and patent litigation literature. We provide evidence that external patents are more likely to successfully protect a product than patents developed within the firm's boundaries. Our results extend the known benefits associated with the markets for technology in boosting innovative performance, and they integrate prior research by offering a new perspective on the role of acquired technologies. Companies can take advantage of external technologies as a defensive strategy to reduce market entry and competition, a result which is in line with that described by Cohen *et al.* (2000). To our knowledge, this is the first paper that separates and analyzes the effects of internal and external patents on both the probability of litigation and the final outcome.

We directed our research questions toward the pharmaceutical industry and the entry of generic manufacturers through the Paragraph IV challenges. Under the U.S.

legislative system, branded firms are granted five years of market protection that runs in parallel with patent protection. After the expiration of the market exclusivity period, generic manufacturers can apply for a Paragraph IV certification and challenge the validity of patents owned by the branded company before its expiration. Generic manufacturers can commercialize their product if they meet one of two conditions: either the generic drug does not infringe on patents held by the branded company or the litigated patents are considered invalid. We argue that Paragraph IV challenges provide a natural setting for our research because they are stochastic events with a binary outcome in that a branded company can either preserve their monopolistic position or lose it in favor of generic manufacturers. This setting offers the possibility to compare internal and external patents as well as their ability to successfully defend the incumbent position in the case of intellectual property lawsuits.

Methodologically, our analysis is divided into two steps. First, we estimate the probability of a company being the target of a Paragraph IV challenge. We focus on both drug and patent level data to analyze the characteristics that influence the decision to challenge a specific drug or patent. Our results show that more profitable drugs have a higher probability of being attacked, thus offering support for existing literature (Grabowski and Kyle, 2007; Higgins and Graham, 2009). However, we do not find differences between internal and external patents on the hazard of being challenged.

Second, we analyze the litigation outcomes of the companies under the Paragraph IV challenge and the likelihood that generic manufacturers win the challenge. We find that acquired technologies reduce the possibility of market entry. In our data, we were unable to identify the method of procurement of the external patents (e.g., licensing or

acquisition); therefore, we classified a patent as external if the company that developed the technology was different from the company that commercialized it. An examination of the litigation outcomes and the effects of external patents lead us to suggest that the due diligence process effectively selects stronger external patents that allow branded firms to maintain their incumbent position.

4.2. Literature review

4.2.1. The role of external technologies

In the last few decades, the importance of external technologies in boosting innovative activity has grown dramatically, and an extensive stream of literature has developed focusing on the role played by technology acquisitions (Arora and Ceccagnoli, 2006; Arora *et al.*, 2001; Arora and Gambardella, 2010; Chesbrough, 2003; Gambardella *et al.*, 2007; Gans *et al.*, 2002; Teece, 1986). In many industries, firms utilize and build on external innovation to maintain their competitive market position, suggesting that markets for technology are a key component of a firm's innovative effort. For instance, Scherer (2010) shows that a larger proportion of revenues for pharmaceutical companies is derived from products discovered outside of the firm. Similarly, Ceccagnoli *et al.* (2010) support this finding in their sample of new drugs introduced into the market: almost half of the patents linked to new products were developed outside the firm. In addition to these findings, products developed through technologies licensed from a biotechnology company tend to have a greater probability of success (Arora and Ceccagnoli, 2006; Danzon *et al.*, 2005). It follows that the role played by external technologies is crucial for the pharmaceutical industry.

Acquired technologies are also important in creating benefits in terms of R&D productivity (Arora *et al.*, 2001). Existing literature tends to converge toward a complementary relationship between internal R&D and external technology acquisitions. Firms with higher levels of internal knowledge are more actively involved in external agreements (Arora and Gambardella, 1990). Similarly, the absorptive capacity of technology buyers is positively related to technology acquisitions (Cassiman and Veugelers, 2006). More recently, Ceccagnoli *et al.* (2011) demonstrate that R&D productivity increases when internal investments and external technologies are combined. These studies emphasize the role of markets for technology from a demand-side perspective, suggesting that licensed technologies generate positive synergies when combined with internal knowledge.

Another benefit of technology acquisitions is related to knowledge spillovers. Through external technologies, firms are able to access knowledge and capabilities that they were lacking. Technology transfers are knowledge flows between the parties involved (Griliches, 1992). Companies can benefit from the know-how transferred from the acquisition by integrating it into the internal knowledge.

Despite the positive effects related to external technologies, there are some obstacles that may affect a company's ability to realize the payoffs generated by technology acquisition. First, contractual uncertainties can undermine the supply of technologies: uncertainty and opportunistic behavior increase transaction costs, reducing technology transfer (Williamson, 1985). Second, the level of tacit knowledge may reduce the positive spillovers generated by the transfer. In fact, when knowledge is difficult to

transfer, the incentive to acquire external technologies is reduced (Kogut and Zander, 1993).

Existing research has extensively focused on either the role of external patents in boosting a firm's innovative effort or on the determinants and conditions that facilitate technology transfers. However, there is no clear result of the reliability of acquired technologies. We question whether firms are able to appropriate the returns generated by external technologies once embedded in commercialized products. After a product is introduced into the market, is there any difference if it relies on internally or externally developed technologies? How is competition affected by the reliability of external patents? In the case of the pharmaceutical industry, one can argue that, relative to internal patents, external technologies may be of lower quality because biotechnology firms have fewer resources and capabilities to develop a stronger and more enforceable patent. However, since pharmaceutical companies perform a due-diligence examination of external patents, the counter explanation would suggest that only technologies with stronger patent protection are selected by the buyer.

4.2.2. Patent Litigation

The market for technology literature emphasizes the benefits of technological acquisitions; however, under the pressure of competitive environments and new entrants, the value of acquired technologies can be affected by the scope of patent protection. In the case of litigation, patents play a crucial role in defending the value of the technology. Previous analyses on optimal patent policy have usually assumed that there is no uncertainty about the scope of patent protection (Gallini, 1984; Gallini and Winter, 1985), but a more recent perspective recognizes that patent protection is imperfect until it

successfully survives a challenge in court (Lemley and Shapiro, 2005; Shapiro, 2003). As Lemley and Shapiro (2005) explain, the strength of patents is linked to the examination process; in general, the structure of patent review favors the approval of weak patents. As a result, almost half of the challenged patents are found invalid when litigated. For this reason, patents have been defined as probabilistic since they do not confer an absolute right to exclude imitators, instead conferring the right to try to exclude them through litigation (Hemphill and Sampat, 2011; Lemley and Shapiro, 2005).

In our context, pharmaceutical companies can exploit external technologies to better protect their R&D investments. According to Katz and Shapiro (1987), stronger patents make licensing more feasible and create disincentives for imitation. The argument behind this logic is that, conditional on a successful development, it may be easier to appropriate the economic rewards of a technology if its patent was held in the early stages. If acquired technologies are more reliable than those developed internally and under a regime of strong patents, pharmaceutical firms may reduce the litigation uncertainty and increase their ability to appropriate the monetary effect of innovation.

Another reason why external patents may be important in the litigation process is based on the opportunity to create complementarities in the patent portfolio. Portfolios of complementary patents can be used as a mechanism to discourage litigation. For example, Lanjouw and Schankerman (2004) identify patent portfolio and owner size as possible factors that determine patent litigation. Their findings show that having a larger portfolio reduces the probability of having a lawsuit filed. The authors conclude that there are enforcement spillovers within a given firm. From this perspective, extensive patenting can lower litigation rates and costs, and promote settlements and patent trades between

the parties involved. Similarly, Bessen and Meurer (2005) analyze patent litigation in the 1980s and 1990s. They identify three reasons why previous work on patent litigation and effectiveness may be misleading: first, patent rates and litigation may be jointly determined; second, effective patent lives may vary across groups; and lastly, the existing literature has focused on litigation as a patent enforcement mechanism and not as a defensive strategy against infringement suits. The effect of patent portfolios as evidenced by Lanjouw and Schankerman (2004) is comparable to what Bessen and Meurer (2005) define as the defensive patenting hypothesis: firms with large portfolios are less likely to sue each other. Finally, Allison and Lemley (1998) focus on patent validity by collecting data on patent and legislation characteristics. They conclude that issued patents have only a slightly higher probability to be valid, and that there is no difference in the likelihood of being invalid between industries.

A different area of research focuses specifically on the determinant of patent settlements. Patent strategies have made litigation unavoidable and, as a result, companies are facing increasing enforcement costs. In fact, since a single product can infringe multiple patents, the number of licenses needed to resolve the disputes has increased. Companies are facing a "patent thicket," requiring them to obtain multiple licensed technologies to commercialize their products (Shapiro, 2001), and are facing a greater risk of litigation. To reduce their enforcement costs, firms can avoid litigation lawsuits by defining settlement agreements on the application of their property rights. Theoretical models have demonstrated how repeated interactions (Allison *et al.*, 2010), suits with negative expected value (Bebchuk, 1987) and imperfect information (Bebchuk, 1984) favor patent settlement. However, even if the parties involved can voluntarily settle

without ending in a lawsuit, the threat of litigation costs can influence the settlement terms and, ultimately, the R&D incentive to develop or acquire new technologies (Hemphill, 2006). Moreover, experienced firms may produce higher quality patents, that gives rise to fewer disputes and lower litigation uncertainty (Graham *et al.*, 2003).

4.3. Pharmaceutical industry and regulatory description

4.3.1. The Pharmaceutical industry

I test the robustness of the second and third hypotheses in Table 3.6a and Table 3.6b (in Chapter 3 Appendix). The former includes the stock of R&D as a measure of absorptive capacity, while the latter includes the stock of scientific references. Similarly to Table 3.4, I present the benchmark regressions estimated on the split samples. The results show that the lack of absorptive capacity and the restrictions imposed by a centralized organizational structure emphasize the substitutability between internal knowledge and licensed technologies.

The pharmaceutical industry provides a perfect setting for our analysis. Because of the U.S. regulatory environment, generic manufacturers can litigate the patents of a branded drug before they expire and undermine the incumbent position of branded companies. Although there is extant literature on generic entry (Grabowski and Kyle, 2007; Reiffen and Ward, 2005; Scott Morton, 2000), there is still little attention on patent challenges and their implications for market entry and competition. A recent stream of research has discussed patent challenges and their role in affecting the length of market protection (Grabowski, 2004; Grabowski and Kyle, 2007; Hemphill and Sampat, 2011). An increasing number of drugs are challenged by generic manufacturers, and drugs with

larger sales attract more competitors (Grabowski and Kyle, 2007; Hemphill and Sampat, 2011; Scott Morton, 1999). A recent paper by Berndt *et al.* (2007) finds similar results on the increasing rate of Paragraph IV certifications. Despite the focus on the impact of authorized generics, which reduces the incentive for entry by new firms, the authors conclude that the number of Paragraph IV challenges remains very high. In addition, this stream of literature suggests that generic challenges are driven by branded drug sales and that, as a consequence of this increase in competition, branded companies face increased uncertainty on returns appropriability as well as a reduction of their R&D incentives. While results converge toward the role played by sales as the primary incentive for generic entry, there is little evidence on the role played by patents and their characteristics in the pre-entry decision and lawsuit outcome.

By combining insights from the existing literature on markets for technology and patent litigation, we analyze the reliability of acquired patents to protect existing products. The literature on markets for technology and patent litigation has discussed the implication of patents on performance and value appropriability. However, they lack the ability to determine if external technologies are more reliable compared to those developed internally. Similarly, existing literature on the pharmaceutical industry has not focused on the role of external patents in court litigations and their use as a defensive mechanism adopted by branded firms to delay market entry by competitors. Several empirical papers have studied generic competition and entry without focusing on the pre-entry decisions (Grabowski and Kyle, 2007; Scott Morton, 1999, 2000). This literature provides important insights on generic entry and its determinants, which include advertising, market size and competition intensity. A recent paper by Hemphill and

Sampat (2011) is the first attempt to our knowledge that links generic patent litigations to patent characteristics. The authors find that, conditional on sales and drug characteristics, weaker patents, defined by citations and family size, are more likely to facilitate Paragraph IV challenges. Therefore, the combination of patents that protect a branded drug may matter in extending the drug's market life. Our intent is to understand under which conditions external patents are challenged by competitors and which patent characteristics can protect the innovation.

4.3.2. The regulatory environment

4.3.2.1. The Hatch-Waxman Act

In the pharmaceutical industry, drug protection was regulated in 1984 with the introduction of the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act. The act was introduced with the intent to establish a balance between innovative pharmaceutical research and access to generic drugs, but it failed to do so. Pharmaceutical companies that seek to market a new chemical-based drug are required to file a New Drug Application (NDA) to the Food and Drug Administration (FDA).[19] The filing process forces pharmaceutical companies to list safety information and effectiveness of the new product. Once a drug is approved, pharmaceutical firms are required to list materially relevant patents in protection of the NDA.[20] The selected patents are listed in the FDA Orange Book, and they define the scope of protection of the

[19] We focus only on chemical-based (non-biological) drugs. Biological drugs are medical products such as vaccines, blood or blood components. They require a Biologics License Application (BLA) and they are approved by the Center for Biologics Evaluation and Research of the FDA.

[20] The FDA Orange Book Preface states the following: "*The patents that FDA regards as covered by the statutory provisions for submission of patent information are: patents that claim the active ingredient(s); drug product patents which include formulation/composition patents; use patents for a particular approved indication or method of using the product; and certain other patents as detailed on FDA Form 3542."* Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm

new drug. Only the patents listed in the Orange Book can be used to protect the drug in case of litigation.

Since the FDA has not precisely defined “materially relevant” innovations and it has not controlled the selection of the listed documents, branded companies enjoy a certain level of freedom in selecting the patent to list in the Orange Book. In addition to patent protection, pharmaceutical companies have historically relied on the ownership of clinical trial results. However, changes in the legal framework and changes in the interpretation of the law by the U.S. courts are affecting patent protection standards and clinical data protection (Knowles, 2010). Therefore, it is important to understand the evolution of the legal environment and how it affects branded companies and generic manufacturers.

In favor of pharmaceutical companies, the Hatch-Waxman Act introduced data exclusively for branded drugs in parallel to patent protection. Data exclusivity is the exclusive marketing right granted upon approval, and it can run concurrently with a patent or not. It protects the ownership of preclinical and clinical trial data. Exclusivity grants differ on protection periods, based on the type of NDA that is approved. Most drugs are approved as new chemical entities and receive 5 years of protection, although orphan drugs are granted 7 years and pediatric drugs are granted an extra 6 months for exclusivity.

The objective of data exclusivity protection is to facilitate the recovery of R&D investments by pharmaceutical companies. In particular, data exclusivity tends to favor new chemical entities with short-term patent protection or none at all. Moreover, the approval process for generic drugs averages about 30 months and the effective protection

is about 7 years. The data exclusivity period is inadequate because of the rising R&D costs; in fact, the average R&D cost of a new branded drug exceeded $800 million in 2000 (DiMasi *et al.*, 2003). Most of the drugs are not able to recoup the entire R&D investment during the exclusivity period, thus reducing the incentive to invest in R&D (Grabowski and Kyle, 2007). After generic drugs enter the market, the market share of branded drugs decreases drastically (Higgins and Graham, 2009), thereby reducing the ability for branded firms to recover their investments. Over the past 25 years, generic products have gone from representing 20% of drug prescriptions to now representing 70% of them (Engelberg *et al.*, 2009). According to Higgins and Graham (2009), aggressive generic competition may result in fewer innovator profits and less incentive to innovate. To reestablish a balance between innovative process and generic access, Knowles (2010) suggests increasing data exclusivity to 14 years to facilitate the recovery of R&D expenditures and to incentivize future investments.

The second intent of the Hatch-Waxman Act was to facilitate generic entry. Under this legislative system, the FDA can approve a new generic drug through an Abbreviated New Drug Application (ANDA). To be approved, generic manufacturers have to demonstrate that their product is bioequivalent to a referenced NDA's brand-name product, which implies that the generic drug has the same active ingredients, dosage form and strength as the NDA. The Hatch-Waxman Act also allows generic manufacturers to use the patents listed in the Orange Book to develop the generic version of the drug before patent expiration.

When generic companies file for an ANDA, they can apply for one of the following patent certifications[21]:

- "Paragraph I certification" pertains to drugs listed in the Orange Book, but without an accompanying patent. The FDA may approve the ANDA immediately.
- "Paragraph II certification" refers to drugs with one or more expired patents. The FDA may approve the ANDA immediately.
- "Paragraph III certification" indicates that generic manufacturers seek approval after the challenged patents have expired. The FDA may approve the ANDA only after such patents expire.
- "Paragraph IV certification" certifies that the listed patents are either invalid or will not be infringed on by the generic drug. ANDA approval is conditional on the Paragraph IV certification outcome.

The process related to Paragraph IV certification is not linear; indeed, it is conditioned by several strategic decisions. The process starts with the Paragraph IV certification request by a generic manufacturer. Paragraph IV applicants are required to list and identify all the patents they want to challenge. As part of the certification, the ANDA filer must notify the patent holder about the certification request and submit a detailed statement of the legal basis by which the generic product does not infringe on the listed patents or a statement detailing why the patents are invalid. A generic product may

[21] In this paper we only focus on Paragraph IV certifications because they challenge the ongoing patent protection. Paragraph IV challenges can be seen as a test of the validity and strength of the patents that protect a branded drug. Other certifications reflect a less competitive choice: under Paragraph I and II, patent protection has already expired therefore new competitors can directly enter the market. Generic manufacturers apply for Paragraph III certifications when patent protection is still active, however the generic version of the drug can be commercialized only after patent protection has expired.

not infringe on the patent if the manufacturer has discovered a way to produce a bioequivalent drug through a different process, has discovered a different structure of the same active ingredient, or has adopted a different delivery mechanism. Alternatively, a patent may be considered invalid if it was wrongfully granted or was anticipated by prior art, or if the invention was in public use for more than 1 year before the USPTO application (Herman, 2011).

After such notice, the patent holder has the option to sue the ANDA filer for infringement within 45 days from the notification. Once the branded company is notified, if a lawsuit is not filed, the FDA can approve the ANDA, and the generic manufacturer may enter the market. In case of infringement, an automatic 30 months' protection is awarded to pharmaceutical companies. During this period, the FDA can only approve the ANDA if there is a court determination of non-infringement, the patent is declared invalid or the patent expires. Conversely, if the lawsuit outcome enforces the patent holder's rights, then generic manufacturers cannot market their products.

When an ANDA filer wins the infringement lawsuit, the Hatch-Waxman Act awards a 180-day exclusivity right to the first Paragraph IV applicant. Under the Hatch-Waxman Act, the definition of first applicant is based on a patent-by-patent system. Therefore, there may be multiple first ANDA filers if they successfully challenge different patents listed in the Orange Book for the same drug. This creates overlapping exclusivity periods called mutual blocking exclusivity. As a result, multiple generic manufacturers may receive the 180-day exclusivity and no one can launch the new product until all overlapping exclusivity periods expire. It has been estimated that the 180-day exclusivity period generates potential revenues of approximately $60 million

(Higgins and Graham, 2009). The costs of challenging are only about $5 million. Clearly, the positive payoff of filing litigation generates high incentives for generic firms to enter the market, thus creating a successful strategy for competing against branded drugs. Figure 4.1 (in Chapter 4 Appendix) summarizes the Paragraph IV certification process.

Under the Hatch-Waxman Act, pharmaceutical companies have developed a peculiar strategy to delay the Paragraph IV outcome by "evergreening," or "stacking" up several 30-month periods (Bulow, 2004). Once litigations are already in progress, pharmaceutical firms are able to list new patents in the Orange Book and effectively restart the 30-month period. In fact, these new patents typically include weak patents that could have been used to sue the ANDA filer for infringement, thereby automatically restarting the 30-month period that prevents generic approval. This strategy is significant in increasing the litigation costs for a Paragraph IV applicant.

To postpone generic entry, another common strategy developed by branded companies is to settle the infringement before a court decision. Such an alternative strategy involves pharmaceutical companies and future competitors that are seeking to market a generic version of the same drug. Settlements may favor both the branded company and the generic manufacturer: pharmaceuticals can maintain their patent-related monopoly, while generics may receive payments for agreeing to end the patent dispute. In short, pharmaceutical firms can settle patent litigations by paying potential competitors to abandon suits that, if successful, would have ruled in favor of the competition. This is advantageous to them because, if the generic manufacturer wins, it can enter the market prior to patent expiration and reduce the market power of pharmaceutical incumbents.

This "pay-for-delay" strategy in the U.S. pharmaceutical industry is very common (Bulow, 2004; Hemphill, 2006). Greater research effort and patenting experience can reduce litigation costs and speed up a possible settlement between parties: pharmaceutical firms may be able to anticipate the lawsuit outcome and determine whether to settle or not and under what conditions. However, the pay-for-delay settlements have raised antitrust concerns because they may limit competition and access to generic drugs. According to a recent study by the U.S. Federal Trade Commission, pay-for-delay settlements cost American consumers $3.5 billion per year.[22]

4.3.2.2.The Medicare Act of 2003

In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) altered the regulatory framework of the Hatch-Waxman Act. The MMA introduced two significant changes. First, it reformed the attribution of the 180-day exclusivity period; only the actual first applicant can receive the 180-day exclusivity for a given drug. This represents a drastic change compared to the previous framework. The shift from a patent-by-patent system to a product-based exclusivity was introduced to avoid mutual blocking exclusivities and to increase the economic incentive of the first ANDA applicant. The new regulation allows for shared exclusivity in case multiple Paragraph IV applicants submit ANDAs to the same drug on the same first day.

Second, the new legal framework introduced a limit of only one 30-month stay period per challenger, thereby limiting the ability of pharmaceutical companies to extend the litigation and increase its cost. As noted by Bulow (2004), pharmaceutical companies

[22] Federal Trade Commission, "How Drug Company Pay-Offs Cost Consumers Billions" (2010) http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf (last accessed: 08/13/2013)

are still listing new patents in the Orange Book because, although they cannot be used to extend the 30-month period, they can still be used in subsequent challenges. Both changes introduced by the MMA shape a new legal system that moves in favor of generic manufacturers. In fact, ANDA filers may use their Paragraph IV applications to exercise, if successful, their exclusivity right as the first applicant, which will allow them to exploit lower litigation costs and briefer lawsuit timeframes through the restriction of the evergreening strategy.

4.3.2.3.The role of the U.S. Supreme Court

As described by (Knowles, 2010), the regulation framework can be modified by both the U.S. Congress with the introduction of new laws and the courts with the application of them. Therefore, when there is a change in the interpretation of the law, patents that were considered valid may become invalid or vice versa. In the last 15 years, three court cases of particular importance have changed the legal regime that regulates Paragraph IV challenges and generic entry. The first case that influenced the regulatory system was the *Mova v. Shalala* case.[23] Before this case, the FDA stated that only a generic applicant that had successfully defended against a patent litigation of the branded company could be awarded the 180-day exclusivity. In 1994, Mova filed a Paragraph IV certification for the generic version of Micronase, a diabetic drug marketed by Pharmacia. Pharmacia responded by suing Mova for infringement. In 1995, when Mylan applied for an ANDA on the same drug, however, Pharmacia declined to sue, and the FDA approved the Mylan generic product. The FDA justified its decision by sustaining

[23] Mova Pharmaceutical vs. Shalala (C.C. Cir. 1998). http://www.gpo.gov/fdsys/granule/USCOURTS-caDC-97-05082/USCOURTS-caDC-97-05082-0/content-detail.html (last accessed: 08/13/2013)

that Mova had not yet successfully defended its right against Pharmacia's lawsuit. At this point, Mova sued the FDA to delay Mylan commercialization. In 1998, the D.C. Circuit affirmed Mova's request to delay Mylan's entry and, as a consequence, changed the legal requirement regarding the *successful defense*. The existing regulation was thus invalid. The FDA revoked the successful defense requirement from its guidance on generic approval. The importance of this case rests on the change of the 180-day exclusivity. The FDA cannot approve new generic versions of the focal drug until the exclusivity of the first applicant has expired. Generic companies now have more incentive to be the first Paragraph IV applicant to benefit from market exclusivity. If the first applicant loses the litigation case, however, under FDA regulation, it must convert its application to a Paragraph III challenge, deeming it ineligible for exclusivity.

The second case changed the evaluation of patent nonobviousness. In 2007, the U.S. Supreme Court decision in *KSR International Co. v. Teleflex, Inc.* affected whether a patent is considered nonobvious given the existing prior art.[24] The context of this case is not related to the pharmaceutical industry; in fact, the case involves the innovation of placing a sensor on a fixed pivot point of an accelerator pedal of an automobile. While the adoption of sensors on automobile pedals was not new, the adoption of a pivot point was the real innovation in the patent owned by Teleflex. At first, the Court of Appeals for the Federal Circuit (CAFC) affirmed the validity of the patent using the teaching, suggestion, or motivation test (TSM test). Under this test, a patent is proved obvious only if there is some motivation or suggestion to combine the prior art that can be already found in said prior art or in the knowledge of a person with ordinary skill in the art.

[24] U.S. Supreme Court Case No. 04-1350. http://www.supremecourt.gov/oral_arguments/argument_transcripts/04-1350.pdf (last accessed: 08/13/2013)

However, the U.S. Supreme Court revised the decision and decided the TSM test was too narrow and rigid. It concluded that an innovation can be obvious even if the prior art does not teach, suggest or motivate the innovation. The Supreme Court considered the Teleflex patent to be obvious and invalid. The Court then introduced a broader and vaguer definition of obviousness based on the use of common sense to one of ordinary skill in the art. With this broader standard, it should be easier for generic companies to prevail in Paragraph IV cases and to demonstrate that the challenged patent is invalid because the court did not specify the meaning of *common sense*. It is possible that patents related to different drug forms, dosages and methods of delivery may be more likely to be rejected and invalidated for obviousness. Chemical compounds often represent new advancements, drug formulations and delivery methods based on existing prior art, thus increasing the likelihood of being invalid.

Finally, the last case involves MedImmune and Genentech. In 1997, MedImmune entered a licensing agreement with Genentech for two patents. One was already issued, while the second patent was a pending application on immunoglobulin host cells. After the agreement, MedImmune successfully commercialized a product called Synagis to treat respiratory disease in young children. By 1999, Synagis represented 80% of MedImmune revenues. In 2001, when the pending patent was granted, Genentech expected MedImmune to pay royalties for the new patent. However, MedImmune believed that Synagis did not infringe on the new patent, and that the same patent was invalid. Nevertheless, MedImmune continued to pay the royalties under protest, as the company did not want to risk losing its most valuable product. Instead, MedImmune brought a declaratory judgment action against Genentech, seeking to invalidate the new

patent. There are two different legislative aspects to consider in this case. First, the *Lear* doctrine (or Licensee estoppel)[25] states that a patent licensee can challenge the validity of a licensed patent only if it refuses to pay royalties. Second, the *declaratory judgment jurisdiction* gives federal courts the authority to declare a party's rights to a case or controversy. At the beginning of 2007, the U.S. Supreme Court reversed the decision made by the Court of Appeals for the Federal Circuit to dismiss the declaratory judgment MedImmune brought against Genentech, thus favoring MedImmune and changing the application of the declaratory judgment doctrine. [26] The implication of this decision is that a Paragraph IV applicant, if not sued, can bring a declaratory judgment action to reduce the uncertainty related by settlements. Rather than being at risk of future litigation suits, generic manufacturers may prefer a declaratory judgment to reduce the uncertainty regarding patent validity. As a result, there may be an increase in declaratory judgments when the branded company does not sue the ANDA filer.

Given the dynamics of the legal environment, understanding the reliability of external patents becomes crucial to protecting the incumbent market position. DiMasi (2000) shows that almost 40% of the FDA-approved drugs from 1963 to 1999 were licensed and, since the introduction of the Hatch-Waxman Act in 1984, generic challenges have drastically increased, which has generated a strong debate on the balance between drug innovation and access (Grabowski, 2004; Higgins and Graham, 2009). The thin balance between drug accessibility and innovation introduced by the Hatch-Waxman act has created concerns that early generic entry may diminish research incentives by reducing patent protection.

[25] Lear, Inc. v. Adkins, 395 U.S. 653 (1969)
[26] U.S. Supreme Court No. 05-608 http://www.supremecourt.gov/oral_arguments/argument_transcripts/05-608.pdf (last accessed: 08/13/2013)

4.4. Data description and methodology

Our sample consists of all the new chemical entities approved by the FDA between 1995 and 2004 and the patents listed in the FDA Orange Book. Although we were able to gather data about drugs and patents from different sources extending to 2010, we limited our analyses to drugs approved through 2004 to allow all our drugs to face the risk of being under the Paragraph IV challenge for at least 1 year. Our sample consists of 773 unique patents and includes 324 unique drugs approved by the FDA between 1995 and 2004.

We matched the drugs and patents collected from the Orange Book to several data sources. First, litigation data was gathered from the proprietary dataset available at www.paragraphfour.com. The Paragraph IV report includes information on the number of Paragraph IV applicants, the products and patents that are being challenged, the status of pending court cases and the court decisions regarding the litigation. Then, we obtained data on sales and promotion expenditures from IMS MIDAS™. Finally, patent data such as the patent approval date, number of claims, citations, and type of patent were collected from Delphion™, IMS Patent Focus™ and the USPTO. We are able to identify if a patent was acquired or internally developed through the reassignment database of the USPTO. We compared the original patent assignee with the company that commercializes the focal drug; if the two were different, we defined that patent as externally developed. It is important to note that we are not able to identify the contractual agreement through which pharmaceutical companies acquired the external technology (e.g., licensing or acquisition). Descriptive statistics and correlations are provided in Table 4.1 and Table 4.2, respectively (both in Chapter 4 Appendix). All

financial variables are converted into constant 2000 US dollars and foreign currencies are converted by using the average 12-month foreign currency divided by the US currency exchange rate.

Our empirical approach is divided into two steps. First, we computed the hazard of a Paragraph IV challenge. We estimated our models both at the drug and the patent level of analysis to identify the characteristics that affect the decision to apply for a Paragraph IV certification. Second, conditional on being under Paragraph IV challenge, we focused on patent characteristics that may affect the litigation outcome in favor of generic manufacturers.

This empirical approach presents several challenges due to multiple selection effects at work. First, branded companies are required to select which external technologies they will buy. Second, after a technology is acquired, there is a selection between which internal and external technologies they will use, followed by their inclusion in the FDA Orange book. Third, generic manufacturers can select which patent to challenge under the Paragraph IV application. All these effects may provide misleading and inaccurate estimates due to omitted variables that differ between treated and untreated groups (e.g., acquired vs. non-acquired patents, FDA-Orange-Book listed vs. non-listed patents, and Paragraph IV-challenged vs. non-challenged patents).

To manage the selection introduced by the technology acquisition process, we estimated the demand for external technologies following Ceccagnoli *et al.* (2010) to define our selection equation and then included the Inverse Mills Ratio in our hazard model estimations. The Inverse Mills Ratio regards the selection of unobservable factors by estimating a bias correction through a choice model, which in our case is the decision

to acquire external technologies. Because the Inverse Mills Ratio is a nonlinear function of the variables included in the choice model, the main equation is identified even if the explanatory variables are identical in the two equations. However, the use of identical regressors posits identification problems because identification occurs on distributional assumptions (normality in the first-stage model) and is not based on variation in the independent variables. In this case, the estimate of the outcome equation may be imprecise. To solve this problem and make the source of identification clear, we follow Wooldridge (2002) and include two independent variables that appear only in the selection equation: *R&D pipeline* and *promotion investments*. The pipeline variable was collected from the Pharmaprojects database, and it includes compounds in development and approved drugs. Prior research has identified marketing capabilities as important co-specialized assets in the pharmaceutical industry (Chan *et al.*, 2007). We collected data on promotion investments from the IMS MIDAS™ database.

The second selection effect cannot be controlled by the data available. The optimal setting requires linking internal and external patents to a specific drug and then estimating the determinants that would lead a patent to be included in the FDA Orange Book. It is impossible to precisely identify the relationship between patents and their application in the drug development process; in other words, we cannot attribute internal and external patents to a specific drug.

Finally, the third selection should not affect our results as, on average, generic manufacturers challenge 85% of patents attached to a branded drug. This behavior should not be surprising since, by challenging multiple patents, the probability that at least one

challenged patent is either invalid or not infringed increases, which in turn increases generic producers' likelihood of entering the market.

4.4.1. Dependent variables

Our data includes three dependent variables. The first variable identifies the *Paragraph IV challenges* at the drug level. We rely on data from www.paragraphfour.com to create a dummy that equals one for a drug that was challenged in a given year between 1999 and 2010, and zero otherwise. We are able to identify a total of 264 unique Paragraph IV challenges. Among our drugs, about 51% experience at least one Paragraph IV challenge, which provides a total of 165 NDAs. In Figure 4.2, there is clearly an increasing trend in the number of drugs challenged every year.

We observe that only 33 drugs have been challenged from 1999 to 2003, while in the subsequent 5 years (2004-2008), this number increases to 132. In just the last 2 years, 99 drugs were challenged. The horizontal lines represent the average number of challenges during three different periods. It is easy to identify the impact of legislative changes on the number of Paragraph IV applications. After the introduction of the MMA in 2003, generic manufacturers embraced Paragraph IV applications as a viable strategy to enter a market favored by lower litigation costs and incentivized by a new exclusivity regime. On average, the number of challenges per year increased to 26.4 in the period from 2004 to 2008, compared to 6.6 in the pre-2003 era. We also observe a shift in the number of drugs challenged after 2008. This increase may be related to the legislative changes introduced by the *KSR* and *MedImmune* cases, which favored generic

manufacturers. The average number of challenges (49.5 challenges) increases by 87% compared to the previous period.

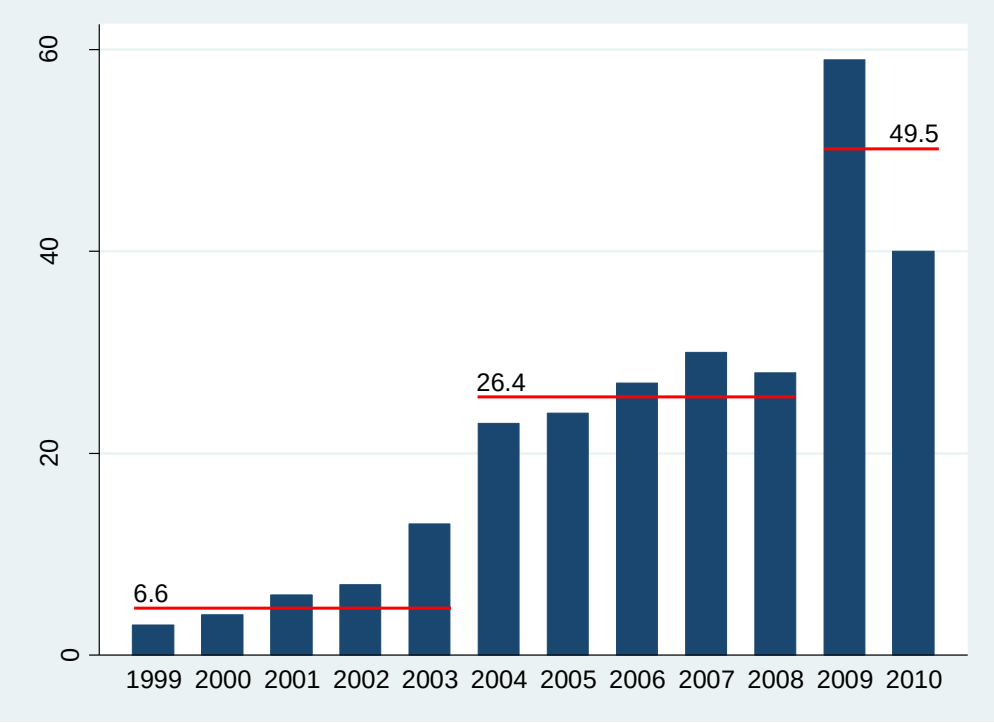


Figure 4.2 Number of unique drugs challenged per year

The second variable is a patent-level dummy that equals one if the ANDA filer challenges the focal patent in a given year and zero otherwise. On average, generic manufacturers challenge almost all patents listed in the FDA Orange Book per drug. In addition, out of the 773 unique patents, 356 of them were challenged at least once in our

data. As shown in Figure 4.3, the distribution of patents per number of Paragraph IV challenges is skewed toward zero. About 17% of our patents (131 patents) received at least two challenges, and 29% (225 patents) were litigated only once.

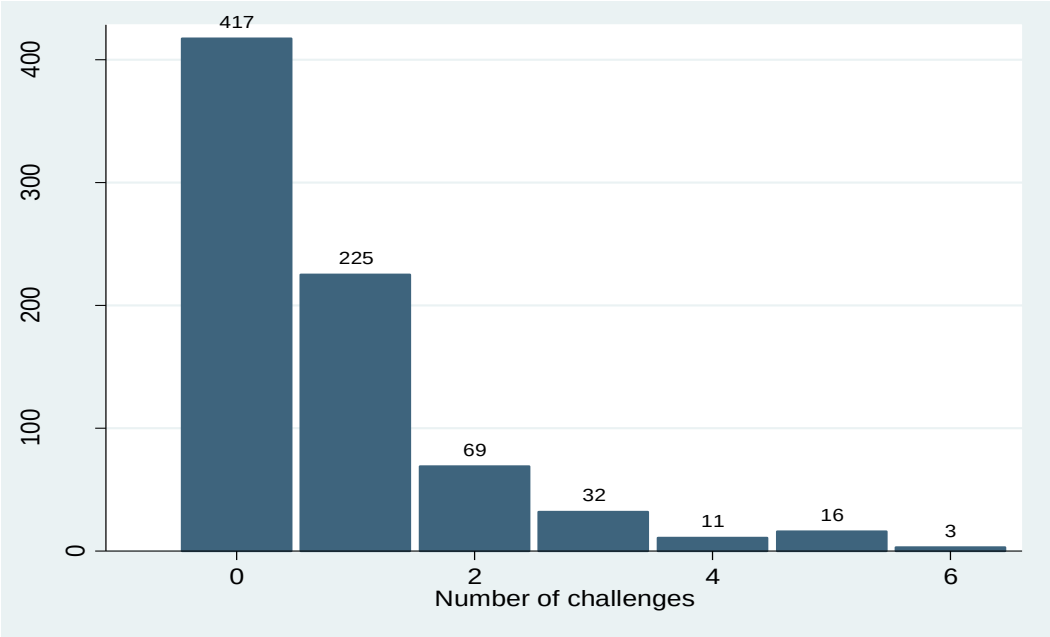


Figure 4.3 Distribution of patents per number of Paragraph IV challenges

Among the 417 patents that received zero litigation, 349 patents are listed for drugs that did not receive any Paragraph IV challenges, while 68 were not challenged but listed under drugs that were litigated. Moreover, 41 of the 68 patents (about 60%) were externally developed, showcasing preliminary support of the idea that external patents may be of higher quality than internal ones.

Our third dependent variable classifies the *Paragraph IV lawsuit outcomes*. We identify two potential scenarios: first, the court decides on the validity of the litigated patents, and second, the companies can privately settle for an agreement. In the latter case, we collected data from companies' statements and SEC filings to identify the terms of the agreements. Finally, we categorized four different outcomes:

1. The court rules in favor of the Paragraph IV applicant. One or more patents listed in the Orange book are considered either invalid or not infringed on by the generic product. It follows that the generic manufacturer can enter the market.
2. The parties settle before reaching court trial. In contrast to the previous case, the agreement allows generic manufacturers to enter as an authorized generic. An authorized generic is a pharmaceutical product that was originally marketed and sold by a brand company, but is re-marketed under a generic product name. Generic companies may choose to partner with the brand company to launch an authorized generic in order to settle litigation or market a product they otherwise might not have been able to launch. We coded this outcome as favorable to generic manufacturers.
3. The parties settle before reaching court trial. The agreement either delays or blocks generic entry. We coded this outcome as favorable to pharmaceutical companies.
4. The court rules in favor of the pharmaceutical company. Patents listed in the Orange Book are considered either valid or infringed by the generic product; as a result, the generic manufacturer cannot enter the market.

To create the outcome dummy variable, we classify the first two cases as favorable to generic manufacturers while the last two cases support branded companies. Therefore, the *Paragraph IV outcome* dummy equals one in case of favorable outcomes for generic manufacturers and zero otherwise. On average, a favorable outcome for generic manufacturers occurs in about 47% of the cases and is almost equally divided between court decisions (63 occurrences) and settlement agreements (61 cases).

4.4.2. Independent variables

We adopt drug sales as one of our drug-level independent variables. Our intent is to study whether more profitable drugs influence the decision for entry by generic companies, since profitable segments attract more competitors. The existing literature has shown that more profitable drugs have a higher probability of being attacked (Grabowski and Kyle, 2007; Higgins and Graham, 2009). Similarly, Caves *et al.* (1991) find that market share is one of the determinants of generic entry. Upon entry, generic companies are able to erode pharmaceutical market share and overcome incumbents (Higgins and Graham, 2009).

The number of *external patents* does not differ from those of internally developed patents; in fact, 383 patents in our sample (about 49%) represent external technologies. Additionally, only 41% of these patents (159 out of 383 external patents) are challenged, compared to 50% of the internal patents (197 out of 390 internal patents). The dummy takes a value of one if a patent was originally assigned to a different firm than the pharmaceutical company that commercializes the drug, and zero otherwise. With the data available, we are not able to identify the method of procurement (e.g., licensing or

acquisition); we can only track changes in patent assignees over time and compare the original assignee with the company that commercialized the branded drug.

To control for different technologies, we include a set of dummies based on the *type of patent*. We rely on the data from the IMS Patent Focus™ database, which describes the function and use of focal patents. Each patent is categorized into one of the following groups: product patent, compound patent, method of use patent, drug delivery system and other types, including process patents. Based on this classification, we create five dichotomous variables. In our sample, about 21% of the patents are products and technologies, about 21% are classified as method of use patents, about 34% of the patents protect the drug composition, 14% are drug delivery system patents, and finally, 10% are classified as other patents. On average, we don't find significant differences in the distribution of patent types between internal and external technologies.

We also include four variables to control for patent characteristics. First, we collected data on both *forward* and *backward* citations. Forward citations are measured by accumulating the number of citations received by a patent from its grant year up to any given year and then representing the impact of the focal patent on subsequent innovations. Backward citations equal the number of existing patents cited. They denote how fundamental and innovative the patent is, since patents with many backward citations extensively build on existing knowledge and therefore may be less innovative. Among the challenged patents, external technologies have significantly fewer backward citations than those developed internally.[27]

[27] On average, external technologies have 14 backward citations while internal patents have 20. The difference is significant at the 10% level.

Second, we use the number of *claims* as a measure of patent quality (Lanjouw and Schankerman, 2004). The principal role of claims is to define the novel features of the invention and detail them to increase patent protection. We construct a variable that counts the total number of claims in all the patents in our sample; we do not find any significant differences between internal and external patents.

Third, following Hemphill and Sampat (2011), we control for the hypotheses that late-expiring patents can add market life to the focal drug and that the timing of patenting may affect generic entry. We generated the *new-patent* dummy which takes a value of one if, within the patent portfolio for a single drug, the grant date of a patent is the latest. By doing so, we are able to trace from a temporal point of view which patents for a specific drug have been granted last. Particularly in the pharmaceutical industry, the timing of technology patenting does not necessarily coincide with its commercialization. Fourth, to control for differences in the lag between the FDA approval (beginning of market exclusivity) and the Paragraph IV challenge, we generate the *extra time* variable that equals the difference between the year of the challenge and the year in which the drug was approved.

We also added a group of variables to control for drug characteristics. Our *patent per innovation* variable controls for the total number of patents attached to the focal NDA in the FDA's Orange Book. By doing so, we take into consideration the different sizes of the patent portfolios for all our drugs. On average, drugs in our sample have four patents listed in the FDA Orange Book, while the largest drug portfolio has 18 patents attached.

Companies may also have different incentives in protecting their products, based on several factors such as drug sales and drug promotion investments. We introduce two

drug importance variables. In particular, we control for the relative importance of the drug for the focal company. The sales variable equals drug sales divided by firm sales in any given year. One can imagine this variable to be the drug market share within the firm boundaries. We control for the drug's relative importance because we assume that, if a Paragraph IV challenge occurs, pharmaceutical companies may be more likely to protect valuable drugs and limit generic entry. By the same token, the promotion variable is computed by dividing the promotion investments for the focal drug by the total firm promotion investments in any given year. Similar to the drug's relative importance, pharmaceutical companies may be more likely to protect drugs whose relative sunk costs are higher. We assume that companies may protect more drugs that are well recognized in the market and that require large marketing investments. We include dummies to control for the *therapeutic area* of the focal drug (ATC).[28] Combined, ATC J (Anti-infective for systemic use) and ATC N (Nervous system) represent 15% of our sample; they are the largest ATCs. The third ATC is ATC A (Alimentary tract and metabolism), which represents about 11% of our drugs.

Given the dramatic change introduced by the MMA, we also included a dummy variable that equals one for all the patents listed in the Orange Book after 2003. With the introduction of the new law, pharmaceutical companies cannot extend the duration of the litigation suit by listing new patents and stacking up multiple 30-month stay periods. In addition, the attribution of the 180-day exclusivity period is now on a drug-based system.

[28] ATC stands for Anatomical Therapeutic Chemical, and its classes are defined by the World Health Organization (http://www.whocc.no/): A, Alimentary tract and metabolism; B, Blood and blood-forming organs; C, Cardiovascular system; D, Dermatological; G, Genitourinary system and sex hormones; H,
Systemic hormonal preparations, excluding sex hormones and insulin; J, Anti-infective for systemic use; L, Antineoplastic and immunomodulating agents; M, Musculoskeletal system; N, Nervous system; P, Antiparasitic products, insecticides and repellents; and R, Respiratory system.

As a consequence, there are more incentives for generic manufacturers to apply early for a Paragraph IV certification.

Finally, we introduced a group of variables to control for Paragraph IV characteristics. We include the total *number of Paragraph IV challengers*. We argue that infringement litigations with multiple challengers are more expensive for branded companies. On average, and conditional on being attacked, a drug has two challengers, while the maximum number of generic manufacturers increases up to 15 for one drug. We also include a dummy to account for challenges that include Teva Pharmaceutical Industries (*Teva dummy*). Teva is the biggest generic company, boasting $16 billion in sales in 2010[29], and it has been extremely active in Paragraph IV challenges. In fact, in our sample, Teva is among the challengers in about 25% percent of the Paragraph IV cases (66 cases out of 264). We build a dichotomous variable that equals one if Teva is among the first group of challengers in a Paragraph IV certification and zero otherwise.

4.5. Results

4.5.1. Probability of receiving a Paragraph IV challenge

4.5.1.1. Drug level estimations

Our first set of analyses examines the determinants of the probability that a branded drug experience a Paragraph IV certification by a generic manufacturer. We estimate the hazard of a Paragraph IV challenge using a semi-parametric hazard model (Cox Model) to account for the correct censoring of the data. Due to the data-building process, the challenges we observe start from 1999 and continue until 2010. In Figure 4.4 (in Chapter 4 Appendix), we report non-parametric estimations of the survival and hazard

[29] http://www.tevapharm.com/en-US/About/Pages/AboutUs.aspx. (last accessed: 09/26/2011)

functions for all our drugs. We compare two groups based on the average drug sales and find preliminary support that sales drive the generic manufacturer's decision to file an ANDA.

The estimated coefficients for different specifications are reported in Table 4.3 (in Chapter 4 Appendix). All our models include both therapeutic and fixed effects. Model 1 includes only our control variables, while Model 2 introduces *drug sales*. The *drug sales* coefficient is positive and statistically significant. This result suggests that a higher level of sales increases the drug's hazard of being challenged. In Model 3, we introduce the *external patents variable*. Its coefficient is statistically not significant in any of our specifications, suggesting that the number of external patents listed in the Orange Book does not affect the hazard of being challenged.

In Models 4 and 5, we introduce several variables to control for patent characteristics. We include the percentage of patent types to account for differences in the composition of the patents attached to a single NDA. In order to control for patent quality, we include the number of claims, backward citations and forward citations received by the average patent attached to the focal drug. None of our variables have an effect in predicting the probability of a Paragraph IV challenge. We then introduce the percentage of patents listed in the Orange Book after the introduction of the MMA and find that these patents increase the hazard of being challenged. Finally, in Model 7, we discover that the patent-type variables positively affect the probability of a challenge when we don't control for drug sales. We don't find this result surprising, given that generic manufacturers tend to litigate most or all the patents listed in the Orange Book.[30]

[30] In our sample, generic manufacturers litigate an average of 85% of the patents listed in the Orange Book for a single drug.

These estimations have two major results: first, sales are the major factor in determining the hazard of Paragraph IV applications, and second, the patents listed after the introduction of the MMA in 2003 increase the chance of a challenge. Not surprisingly, sales have the strongest effect on the hazard of a challenge. These results support the existing literature, which posits that generic manufacturers enter markets with a higher expected value (Grabowski, 2004; Grabowski and Kyle, 2007; Hemphill and Sampat, 2011; Higgins and Graham, 2009; Scott Morton, 1999). As demonstrated by Higgins and Graham (2009), the first generic producer to enter the market is granted 180 days of market exclusivity, which translates into $60 million in profits. Therefore, there is a larger incentive to attack and focus more on profitable drugs than on technology-advanced ones. In addition, we find support for the idea that the MMA favors generic entry by reducing litigation costs, because drugs with a higher percentage of patents listed after 2003 experience a higher challenge hazard. It is possible that generic manufacturers are increasing their Paragraph IV challenges to exploit the exclusivity right assigned to the first challenger.

4.5.1.2. Patent level estimations

In our second set of analyses, we estimate the hazard of Paragraph IV challenges, but we use our data at the patent level. Analyzing patent-level data may introduce a selection effect bias, since companies tend to acquire only the "best" technologies available. Companies' technology demands can be affected by factors such as complementary assets, technological productivity, technology generality, and firm size, among others (Ceccagnoli *et al.*, 2010; Gambardella *et al.*, 2007). We included the

Inverse Mills Ratio in our specifications to account for selection bias. However, we do not find strong statistical evidence of the selection choice.

Our new estimations are reported in Table 4.4 (in Chapter 4 Appendix). Models 1 to 6 report the estimations without interaction effects, while Models 7 to 12 include our patent characteristic variables interacted with the external patent dummy. Our linear regressions confirm the results we find in the Paragraph IV analyses at the drug level. In particular, we do not find different effects between external and internal patents. Patent-type variables may increase the chance of a challenge when we don't control for sales. We also confirm that sales drive most of the variance in explaining generic challenges. Finally, we find a positive effect of the introduction of the MMA, thus confirming that the reform reduces the litigation costs and favors generic entry (Models 5 and 6). Moreover, the effect of this act is significant for both internal and external patents (Models 10 to 12). Similarly to the drug-level analyses, these results confirm that the MMA has favored the increase of Paragraph IV challenges. Generic manufacturers have more incentive to be among the first applicants, since they would retain the exclusivity right; also, the limit of only one 30-month stay has lowered litigation costs.

In addition, our results suggest that a higher number of claims increases the hazard of challenge. Since generic manufacturers seek to demonstrate that listed patents are invalid, a higher number of claims may indicate an "overclaiming" effect (Allison *et al.*, 2010). It may be the case that the scope of listed patents is too broad; if so, the patents in question are more likely to be found invalid or not infringed. Finally, similar to Hemphill and Sampat (2011), higher numbers of patents per drug positively increase the likelihood of a challenge.

In Models 7 to 12, we interact patent variables with the external patent dummy in an attempt to identify possible differences in patent characteristics between internal and external patents. As described in previous estimations, patent-type variables are significant only if we do not include sales in the estimation. For these variables, we do not find a clear contraposition between internal and acquired patents; however, the increase in the hazard of challenge is driven by internal patents.

A second interesting result confirms the possible effect of overclaiming. While we still find a positive effect in the hazard of a challenge, we also find that this effect is driven by external patents. When we interact the claims with the external patent dummy, we find a positive and significant coefficient, while the linear effect has no effect. This result suggests that external patents may use claims to overdefine the scope of protection.[31] Generic manufacturers may exploit overclaiming patents to seek invalidity and/or be granted the ANDA approval.

4.5.2. Paragraph IV outcomes

After generic manufacturers decide to apply for a Paragraph IV challenge, the actual possibility of entering the market is defined by either a positive outcome of the litigation suit or a settlement with the pharmaceutical firm.[32] It is important to understand the role of patents in determining the lawsuit outcome for each challenge.

Our regressions are estimated using a semi-parametric Cox Hazard Model. Our hazard variable equals one if generic manufacturers are able to enter the market by either

[31] On average, external patents have three claims more than internal ones. The same result holds if we limit our test only to litigated patents. These differences are statistically significant, confirming the possibility of overclaiming for external patents.

[32] Generic manufacturers can enter the market before the court ruling. However, generic producers must weigh the benefits and risks of an at-risk launch in order to minimize possible downstream risks in case the court rules in favor of the pharmaceutical company.

winning the litigation suit or signing an agreement with the branded company to become an authorized generic. The variable equals zero when the court rules in favor of branded companies, litigated patents are valid and/or infringed, or pharmaceutical companies adopt a pay-for-delay strategy (Hemphill, 2006). To account for the reliance on external technologies, we include the Inverse Mills Ratio, estimated from the technology demand equation; however, we still do not find a significant effect. Table 4.5 (in Chapter 4 Appendix) reports the estimated coefficient of our Paragraph IV outcome regressions.

As in the previous section, Models 1 to 5 report the linear effects of our measures while Models 6 to 10 include the interacted variables with the external patent dummy. Our main variable of interest, *external patent*, has a negative effect on the hazard of generic wins in all our linear models in Table 4.5. This result confirms the possibility that acquired technologies may be more reliable than those developed internally. On average, external patents are less likely to favor generic entry through a Paragraph IV certification. We are unable to find the same effect when we introduce our interaction variables. One can imagine that external patents are more reliable because they represent the "best" patents available to protect the innovation. Based on previous studies on markets for technology, pharmaceutical companies use internal and external patents to boost their innovative productivity (Arora *et al.*, 2001; Cassiman and Veugelers, 2006; Ceccagnoli *et al.*, 2011; Chesbrough, 2003). However, among the entire pool of patents used to develop a new drug, pharmaceutical companies select only a few to be listed in the Orange Book. Based on this process, firms should select those patents that guarantee the highest level of protection. Although we control for the possible selection induced by the company's

technological demand, in our data we cannot account for the selection of the patents listed in the Orange Book.

The average effect of our measure of patent types reduces the possibility of a favorable outcome for a generic manufacturer. While these types of patents are more likely to be challenged, they do not guarantee a positive outcome for the Paragraph IV applicant. In addition, given the results of our models with interactions, the negative effect seems to be driven only by internal patents.

Surprisingly, we do not find evidence of an increase in the hazard of generic wins when litigated patents are listed after the introduction of the MMA. If it is true that patents listed after a litigation has begun are weaker patents (Bulow, 2004), then one would expect an increase in the probability of them being either invalid or not infringed. By allowing only one automatic 30-month stay period, the Medicare reform has reduced the litigation costs and, in turn, increased the generic incentives to apply for a Paragraph IV certification. However, the reform has not affected the possibility of a successful Paragraph IV application.

Interestingly, we find that patent characteristics such as claims and forward citations have no effect on the lawsuit outcomes. In contrast, a higher number of backward citations positively increases the hazard of a generic win. Patents with more backward citations may be less innovative since they rely more extensively on existing technologies; therefore, it may be easier to demonstrate the invalidity of the patents. Following Lanjouw and Schankerman (2004), we also believe that the "insignificance" of patent characteristics is still an important result. In particular, it may be possible that lawsuit outcomes are independent of observed characteristics of patents (Lanjouw and

Schankerman, 2004). Similarly, (Allison and Lemley, 1998) find no significant patent variables among their covariates that affect the validity of patent lawsuits. They suggest that possible explanatory variables should include the use of experts and witnesses, the skills of lawyers and the amount of money spent on litigation.

While we are unable to control for other lawsuit variables as suggested by Allison and Lemley (1998), we are able to proxy the willingness to protect the drug by using the relative drug importance at the sales and promotion level. We assume that pharmaceutical firms would adopt a more aggressive defensive strategy, like hiring more skilled lawyers, for drugs that represent a high volume of sales or have benefited from higher levels of sunk costs such as promotion investments. Our findings confirm that only the relative investment in promotions has a negative effect on the hazard of generic entry. We conclude that pharmaceutical companies tend to give higher protection to those drugs with high levels of marketing costs.

As expected, we find that the hazard of a successful Paragraph IV application increases with the number of challengers. Pharmaceutical companies may face litigation costs that are too high when more than one applicant is involved in the lawsuit. Finally, if TEVA Pharmaceutical is among the Paragraph IV challengers, the likelihood of a generic win increases. This result can be explained by the peculiar strategy adopted by TEVA, which tends to challenge an extensive number of drugs without focusing on specific markets. It is possible that TEVA has developed unique experiences and capabilities that it can exploit during the litigation process.

4.6. Discussion and conclusion

By relying on the markets for technology and patent-litigation streams of literature, our study provides novel insights on the role of acquired technologies and on the impact of policy changes in patent litigations. First, we find evidence that external patents are more reliable than those developed internally. In fact, our results suggest that external technologies reduce the possibility that generic manufacturers are able to successfully defend their Paragraph IV applications. It follows that acquired patents can delay competitors' market entry. However, they are not able to prevent or reduce the hazard of patent litigations. Second, we find evidence that the introduction of the MMA increased patent litigations in the pharmaceutical industry. Third, we support prior findings of the dominant role of sales in increasing the incentives of generic producers to enter the market.

We use a unique dataset on patent litigations to examine whether external patents are more reliable than those developed internally. Our empirical context is the pharmaceutical industry and litigations regulated under the Paragraph IV certifications requested by generic manufacturers. This paper expands our understanding of the importance of acquired patents in protecting future downstream revenues. It is commonly accepted that acquired technologies can increase innovative productivity, generate knowledge spillovers and create unique synergies with existing internal competences (Arora and Ceccagnoli, 2006; Arora *et al.*, 2001; Cassiman and Veugelers, 2006; Ceccagnoli *et al.*, 2011; Gans *et al.*, 2002). However, there is a lack of explorative research on the reliability and strength of external technologies in the case of patent litigation.

The empirical analyses support the idea that acquired patents may be of higher quality than those developed internally. We find evidence that external technologies reduce the possibility that generic manufacturers enter the market prior to patent expiration. There are two possible explanations for this result. First, pharmaceutical companies can effectively select the best patent available in the market (Arora *et al.*, 2009). As new branded drugs are introduced under the early threat of generic entry, the required level of innovativeness should be very high to maintain a dominant market position and reduce generic competition. It follows that the role played by external technology becomes crucial in protecting marketed products and the stream of future revenues generated by the new product. Backward citations represent the innovative step of the new technology and measure how much the innovation relies on prior art (Lemley and Shapiro, 2005). Among the challenged patents, the difference in the average numbers of backward citations supports the idea that external technologies may be of better quality. In fact, external patents include only 14 backward citations compared to the internal patents that include 20. It follows that a lower number of backward citations characterizes more innovative technologies that may be less likely to be considered invalid when confronted with Paragraph IV challenges.

Second, a successful patent scrutiny process may favor the selection of patents that strengthen the innovative process by creating synergies with internal capabilities (Cassiman and Veugelers, 2006; Ceccagnoli *et al.*, 2011) and helping to fulfill production pipelines (Higgins and Rodriguez, 2006). The due diligence performed by branded companies allows the selection of patents that complement internal technologies; external technologies may be able to fill the gaps left from internal patent protection. As pointed

out by Lanjouw and Schankerman (2004), companies can enjoy “enforcement spillovers” by combining multiple patents to increase portfolio size, thus reducing litigation uncertainty. The growth in portfolio size through external patents increases the bargaining power of branded firms, which can leverage their position with regard to the potential threat of entrants.

Our results also provide an empirical test of the impact of the MMA. The regression analyses confirm that the introduction of the new legislation has favored the increase of Paragraph IV challenges by lowering litigation costs and uncertainty for generic manufacturers, although it didn’t have any effect on the litigation outcomes. The lack of results on court decisions should not be surprising, given the scope of the legislation. In fact, the MMA had two primary effects that didn’t change the court's decision process. First, it modified the attribution of the 180-day exclusivity from a patent-by-patent system to a product-based system, incentivizing a litigation race by generic manufacturers. Second, based on our results, the legislation successfully limited the evergreening strategy. Generic manufacturers face lower litigation costs and briefer wait times since pharmaceutical companies are not able to strategically manipulate the system by listing additional patents in the Orange Book to obtain an extension of the 30-month stay period (Bulow, 2004). As a consequence, the MMA increased the incentive to initiate a Paragraph IV certification but it did not regulate the legal environment in ways that might affect the litigation outcome.

Finally, we confirm the importance of sales as a primary incentive to enter the Paragraph IV challenge. Prior studies have already demonstrated the importance of sales for generic entry in general (Scott Morton, 1999, 2000) or after patent expiration

(Grabowski and Kyle, 2007). It has also been shown that sales affect the intensity of challenges, conditional on a challenge occurring (Berndt *et al.*, 2007; Hemphill and Sampat, 2011). Our empirical evidence supports the idea that sales are the most important incentive for Paragraph IV challenges. Generic manufacturers target more profitable markets. In particular, the first generic entrant can gain substantial benefits from the 180-day exclusivity period granted by the current legislation (Higgins and Graham, 2009).

Our approach provides a better understanding of the reliability of acquired patents by integrating the choice of market entry with the markets for technology. Our findings suggest that external patents do not influence the decision to initiate patent challenges. However, they significantly increase the probability of winning a lawsuit which, in turn, prevents market entry. We also find that the introduction of the MMA has lowered litigation costs for generic manufacturers and increased the hazard of being challenged. The results of the MMA suggest that generic manufacturers can take advantage of this new legislation that has lowered the barriers to entry.

In the context of the pharmaceutical industry, the implications of these policy changes are reflected in potential welfare increases for consumers. For example, in the hypertension market, Branstetter *et al.* (2011) find that consumers benefit from a total of $92 billion due to Paragraph IV generic entries, while pharmaceutical producers lose approximately $14 billion. In the short run, these results suggest a potential benefit to the society, but in the long run, the prospect of limited profitability of new drugs may reduce pharmaceutical incentives to invest in R&D and develop new and innovative drugs.

CHAPTER 4 APPENDIX

Table 4.1. Descriptive statistics

Variable	Observation	Mean	Std. Dev.	Min	Max
Paragraph IV (drug level)	8257	0.093	0.291	0	1
Paragraph IV (patent level)	8257	0.072	0.259	0	1
Paragraph IV outcome	718	0.491	0.501	0	1
Sales	8257	333,039.6	823,264.4	0	8,216,271
External technology	8257	0.492	0.499	0	1
backward citation	8257	17.292	37.867	0	276
Claims	8257	20.454	22.342	1	396
Forward citation	8257	21.451	32.982	0	387
Medicare Act	8257	0.294	0.456	0	1
Patent per Innovation	8257	4.127	3.086	1	18
Method Patent	8116	0.191	0.393	0	1
Composition patent	8116	0.328	0.469	0	1
Drug Delivery patent	8116	0.135	0.341	0	1
Product Patent	8116	0.264	0.441	0	1
Extra-time	8257	5.673	3.540	0	15
Newest patent	8257	0.454	0.497	0	1
Challengers	8257	0.171	0.803	0	15
Teva	8257	0.023	0.152	0	1
Relative drug importance	8017	0.105	0.220	0	1
Relative sunk cost	7928	0.115	0.223	0	1

Table 4.2. Correlation Table

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
1.Paragraph IV (patent level)	1																		
2.Paragraph IV outcome	-0.030	1																	
3.Sales	-0.045	-0.054	1																
4.External technology	-0.062	-0.037	-0.040	1															
5.Backward citation	0.077	-0.021	-0.123	-0.051	1														
6.Claims	0.064	-0.071	0.031	0.130	0.327	1													
7.Forward citation	-0.160	-0.003	0.201	0.062	-0.115	-0.030	1												
8.Medicare Act	0.134	-0.138	-0.211	0.092	0.175	0.204	-0.064	1											
9.Patent per Innovation	-0.091	0.153	0.463	-0.096	0.083	0.107	0.006	-0.022	1										
10.Method Patent	0.063	0.046	0.007	-0.068	-0.075	0.043	-0.149	0.007	0.141	1									
11.Composition patent	-0.017	0.021	0.016	-0.038	-0.059	-0.004	0.000	0.072	-0.091	-0.432	1								
12.Drug Delivery patent	-0.016	-0.029	-0.180	0.147	0.379	0.110	0.001	0.073	-0.025	-0.221	-0.287	1							
13.Product Patent	-0.048	-0.056	0.113	0.000	-0.145	-0.122	0.175	-0.154	-0.025	-0.316	-0.412	-0.210	1						
14.Extra-time	0.098	-0.055	0.185	-0.120	0.015	-0.077	0.001	-0.369	-0.015	0.049	-0.108	-0.038	0.101	1					
15.Newest patent	0.145	0.036	-0.112	-0.073	-0.028	0.019	-0.221	0.079	-0.308	0.127	0.102	-0.086	-0.173	-0.010	1				
16.Challengers	0.119	0.193	0.096	-0.038	-0.050	-0.034	0.024	0.031	0.003	0.014	0.007	-0.054	-0.001	-0.081	-0.004	1			
17.Teva	0.061	-0.052	0.046	-0.032	-0.086	-0.008	-0.004	0.071	0.016	-0.026	-0.012	-0.062	0.090	-0.094	-0.010	0.148	1		
18.Relative drug importance	0.020	-0.040	0.325	0.015	-0.048	0.010	-0.007	0.034	0.314	0.239	-0.112	-0.096	-0.033	0.027	-0.043	0.027	0.054	1	
19.Relative sunk cost	0.048	-0.074	0.111	-0.007	-0.004	0.007	-0.044	0.178	0.242	0.193	-0.117	-0.041	-0.014	-0.120	-0.068	-0.009	0.121	0.766	1

Table 4.3 Hazard model of Paragraph IV application (drug level)

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Sales (log)		0.379***	0.382***	0.392***	0.403***	0.409***	
		(0.0608)	(0.0615)	(0.0639)	(0.0642)	(0.0671)	
External Patents (%)			0.114	0.167	0.147	0.0881	-0.0450
			(0.177)	(0.179)	(0.171)	(0.183)	(0.201)
Medicare Act						0.932***	0.889***
						(0.200)	(0.198)
Method Patents (%)					0.766*	0.617	1.091**
					(0.439)	(0.424)	(0.490)
Composition Patents (%)					0.660	0.499	1.010**
					(0.437)	(0.438)	(0.477)
Drug Delivery Patents (%)					0.544	0.524	0.963**
					(0.454)	(0.434)	(0.469)
Product Patents (%)					0.0533	-0.0385	0.814*
					(0.423)	(0.428)	(0.470)
Claims (Avg.)				0.001	-0.002	-0.006	-0.004
				(0.009)	(0.009)	(0.008)	(0.008)
Back Citations (Avg.)				0.003	0.004	0.003	0.003
				(0.002)	(0.003)	(0.003)	(0.003)
Forward Citations (Avg.)				-0.007	-0.006	-0.003	0.00001
				(0.005)	(0.005)	(0.005)	(0.005)
New Patents (Count)	0.106	0.0964	0.103	0.0706	0.0332	0.0950	0.0980
	(0.206)	(0.196)	(0.197)	(0.190)	(0.181)	(0.183)	(0.201)
Patent per Innovation	0.0687	0.0138	0.0139	0.0154	0.0128	-0.0243	0.0383
	(0.0465)	(0.0386)	(0.0388)	(0.0381)	(0.0388)	(0.0364)	(0.0476)
Extra-time	0.0303	0.0103	0.0138	-0.00001	-0.0441	-0.0960*	-0.0437
	(0.0627)	(0.0570)	(0.0565)	(0.0573)	(0.0578)	(0.0537)	(0.0608)
ATC Fixed Effect	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effect	Yes	Yes	Yes	Yes	Yes	Yes	Yes
N	3336	3336	3336	3336	3336	3336	3336
Log-Likelihood	-1326.1	-1283.3	-1283.1	-1281.2	-1277.4	-1267.2	-1311.7
Cluster	324	324	324	324	324	324	324

Clustered standard errors in parentheses, Coefficient are reported
* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

Table 4.4 Hazard model of Paragraph IV application (patent level)

	(1)	(2)	(3)	(4)	(5)	(6)
Sales (log)						0.369***
						(0.0547)
External Patents		-0.156	-0.183	-0.162	-0.197	-0.196
		(0.145)	(0.144)	(0.141)	(0.142)	(0.140)
Medicare Act					0.612***	0.802***
					(0.141)	(0.140)
Product Patents				1.683**	1.567**	0.348
				(0.654)	(0.660)	(0.546)
Drug Delivery Patents				2.290***	2.041***	0.484
				(0.742)	(0.755)	(0.669)
Composition Patents				1.114**	1.061**	0.693*
				(0.516)	(0.506)	(0.394)
Method Patents				1.783***	1.619**	0.459
				(0.659)	(0.665)	(0.535)
Claims			0.006***	0.007***	0.006***	0.002*
			(0.002)	(0.002)	(0.001)	(0.001)
Back Citations			-0.001	-0.007***	-0.006***	0.002
			(0.001)	(0.002)	(0.002)	(0.002)
Forward Citations			-0.001	-0.001	-0.001	-0.001
			(0.001)	(0.001)	(0.001)	(0.001)
New Patents	0.214*	0.205*	0.171	0.151	0.0734	0.0272
	(0.111)	(0.113)	(0.117)	(0.120)	(0.119)	(0.110)
Patent per Innovation	0.0977***	0.0926***	0.0824***	0.0823***	0.0608**	-0.0344
	(0.0312)	(0.0314)	(0.0313)	(0.0300)	(0.0295)	(0.0273)
Inverse Mills Ratio	1.263	1.012	1.549	9.238***	7.319***	-1.932
	(0.928)	(0.996)	(1.109)	(2.617)	(2.716)	(2.938)
ATC Fixed Effect	Yes	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effect	Yes	Yes	Yes	Yes	Yes	Yes
N	4810	4810	4810	4810	4810	4810
Log-Likelihood	-3192.2	-3191.5	-3186.3	-3175.1	-3164.3	-3120.7
Cluster	468	468	468	468	468	468

Standard errors in parentheses
* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

Table 4.4 Hazard model of Paragraph IV application (patent level) - Continued

	(7)	(8)	(9)	(10)	(11)	(12)
Sales (log)						0.366***
						(0.053)
External Patents	-0.125	-0.328*	-0.0646	-0.403**	-0.704	-0.499
	(0.154)	(0.184)	(0.818)	(0.182)	(0.744)	(0.658)
Medicare Act				0.421***	0.422***	0.619***
				(0.149)	(0.151)	(0.144)
Medicare Act x External Patents				0.555**	0.578**	0.555**
				(0.233)	(0.256)	(0.248)
Product Patents			1.711**	1.635***	1.658**	0.397
			(0.738)	(0.631)	(0.694)	(0.559)
Product Patents x External Patent			-0.181		0.0938	-0.0314
			(0.846)		(0.732)	(0.646)
Drug Delivery Patents			2.348***	2.106***	2.347***	0.468
			(0.860)	(0.716)	(0.809)	(0.702)
Drug Delivery Patents x External Patent			-0.207		-0.0948	0.118
			(0.958)		(0.777)	(0.692)
Composition Patents			1.099*	1.093**	1.008*	0.644
			(0.605)	(0.487)	(0.572)	(0.422)
Composition Patents x External Patent			0.00856		0.262	0.218
			(0.856)		(0.734)	(0.647)
Method Patents			1.806**	1.689***	1.740**	0.595
			(0.737)	(0.631)	(0.690)	(0.538)
Method Patents x External Patent			-0.182		0.0213	-0.251
			(0.907)		(0.796)	(0.699)
Claims		0.001	0.007***	0.006***	0.001	-0.001
		(0.002)	(0.001)	(0.001)	(0.003)	(0.008)
Claims x External Patent		0.006***			0.008**	0.006**
		(0.002)			(0.003)	(0.002)
Back Citations		0.001	-0.006***	-0.005***	-0.006**	0.002
		(0.001)	(0.002)	(0.002)	(0.002)	(0.002)
Back Citations x External Patent		-0.004			-0.005	-0.007
		(0.005)			(0.005)	(0.004)
Forward Citations		-0.003	-0.001	-0.001	-0.003	-0.001
		(0.004)	(0.001)	(0.001)	(0.003)	(0.002)
Forward Citations x External Patent		0.004			0.005	0.002
		(0.004)			(0.004)	(0.003)
New Patents	0.230*	0.150	0.154	0.062	0.074	0.034
	(0.127)	(0.122)	(0.122)	(0.117)	(0.136)	(0.126)
New Patents x External Patent	-0.0770				-0.0707	-0.0596
	(0.261)				(0.285)	(0.260)
Patent per Innovation	0.092***	0.080**	0.0833***	0.056*	0.052*	-0.039
	(0.031)	(0.030)	(0.030)	(0.029)	(0.029)	(0.027)
Inverse Mills Ratio	1.026	1.632	8.916***	7.773***	8.428***	-1.546
	(0.985)	(1.123)	(2.648)	(2.592)	(2.519)	(2.864)
ATC Fixed Effect	Yes	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effect	Yes	Yes	Yes	Yes	Yes	Yes
N	4810	4810	4810	4810	4810	4810
Log-Likelihood	-3191.4	-3183.9	-3174.8	-3161.5	-3157.7	-3115.9
Cluster	468	468	468	468	468	468

Standard errors in parentheses, * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

Table 4.5 Hazard model of lawsuit outcome (patent level)

	(1)	(2)	(3)	(4)	(5)
External Patents		-0.558***	-0.552***	-0.690***	-0.683***
		(0.181)	(0.185)	(0.205)	(0.203)
Medicare Act					0.408
					(0.248)
Product Patents				-2.344***	-2.154**
				(0.876)	(0.847)
Drug Delivery Patents				-2.699**	-2.396**
				(1.240)	(1.184)
Composition Patents				-0.783***	-0.664**
				(0.263)	(0.301)
Method Patents				-2.645***	-2.471***
				(0.837)	(0.801)
Claims			0.001	-0.005	-0.005
			(0.002)	(0.003)	(0.003)
Back Citations			0.001	0.012**	0.010**
			(0.001)	(0.005)	(0.005)
Forward Citations			-0.001	0.001	0.001
			(0.001)	(0.002)	(0.002)
New Patent	-0.0555	-0.121	-0.127	-0.0761	-0.160
	(0.0988)	(0.100)	(0.108)	(0.116)	(0.118)
Patent per Innovation	0.0775	0.0358	0.0350	0.0417	0.0174
	(0.0600)	(0.0568)	(0.0574)	(0.0583)	(0.0612)
Teva	0.489**	0.608***	0.603***	0.721***	0.732***
	(0.209)	(0.212)	(0.213)	(0.215)	(0.212)
Number of Challengers	0.123*	0.128*	0.128*	0.145*	0.107
	(0.0706)	(0.0692)	(0.0693)	(0.0768)	(0.0853)
Drug importance (sales)	-0.993	-1.048	-0.992	-0.370	-0.230
	(0.757)	(0.777)	(0.759)	(0.824)	(0.840)
Drug importance (promotion)	-8.124***	-8.122***	-8.158***	-8.030***	-7.926***
	(0.701)	(0.713)	(0.703)	(0.708)	(0.740)
Inverse Mills Ratio	-0.505	-0.968	-1.005	-17.41**	-16.61**
	(1.133)	(1.156)	(1.250)	(7.148)	(6.678)
ATC Fixed Effect	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effect	Yes	Yes	Yes	Yes	Yes
N	428	428	428	428	428
Log-Likelihood	-1122.4	-1118.3	-1118.2	-1112.3	-1110.7
Cluster	231	231	231	231	231

Standard errors in parentheses
* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

Table 4.5 Hazard model of lawsuit outcome (patent level) - Continued

	(6)	(7)	(8)	(9)	(10)
External Patents	-0.514***	-0.529***	-0.574**	-0.682***	-1.062*
	(0.164)	(0.202)	(0.269)	(0.204)	(0.627)
Medicare Act				0.408*	0.352
				(0.242)	(0.237)
Medicare Act x External Patents				-0.00167	0.344
				(0.299)	(0.355)
Product Patents			-2.447***	-2.152**	-2.292***
			(0.918)	(0.846)	(0.850)
Product Patents x External Patent			0.00263		0.489
			(0.320)		(0.635)
Drug Delivery Patents			-3.233**	-2.392**	-3.220**
			(1.462)	(1.183)	(1.286)
Drug Delivery Patents x External Patent			0.407		1.189
			(0.763)		(0.893)
Composition Patents			-0.754***	-0.663**	-0.708**
			(0.271)	(0.310)	(0.286)
Composition Patents x External Patent			-0.151		0.343
			(0.390)		(0.672)
Method Patents			-2.594***	-2.468***	-2.411***
			(0.859)	(0.799)	(0.789)
Method Patents x External Patent			-0.539		-0.170
			(0.444)		(0.665)
Claims		-0.001	-0.006	0.006***	-0.006*
		(0.002)	(0.003)	(0.001)	(0.004)
Claims x External Patent		0.006			0.005
		(0.006)			(0.005)
Back Citations		0.001	0.014**	0.010**	0.014**
		(0.001)	(0.006)	(0.005)	(0.006)
Back Citations x External Patent		-0.020			-0.016
		(0.021)			(0.018)
Forward Citations		-0.001	0.001	0.001	0.001
		(0.002)	(0.002)	(0.002)	(0.003)
Forward Citations x External Patent		0.002			-0.001
		(0.003)			(0.004)
New Patent	-0.083	-0.088	-0.097	-0.005	-0.140
	(0.092)	(0.106)	(0.106)	(0.117)	(0.107)
New Patent x External Patent	-0.141				-0.149
	(0.314)				(0.381)
Teva	0.607***	0.648***	0.714***	0.732***	0.730***
	(0.213)	(0.220)	(0.211)	(0.212)	(0.207)
Number of Challengers	0.126*	0.131*	0.157**	0.107	0.117
	(0.0699)	(0.0692)	(0.0760)	(0.0860)	(0.0846)
Drug importance (sales)	-1.024	-0.780	-0.306	-0.230	0.106
	(0.769)	(0.772)	(0.798)	(0.868)	(0.798)
Drug importance (promotion)	-8.084***	-8.389***	-8.062***	-7.926***	-8.121***
	(0.696)	(0.723)	(0.741)	(0.724)	(0.770)
Inverse Mills Ratio	-0.880	-0.812	-18.17**	-16.61**	-16.77**
	(1.144)	(1.237)	(7.313)	(6.709)	(6.689)
ATC Fixed Effect	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effect	Yes	Yes	Yes	Yes	Yes
N	428	428	428	428	428
Log-Likelihood	-1118.2	-1116.8	-1111.5	-1110.7	-1108.6
Cluster	231	231	231	231	231

Standard errors in parentheses, * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

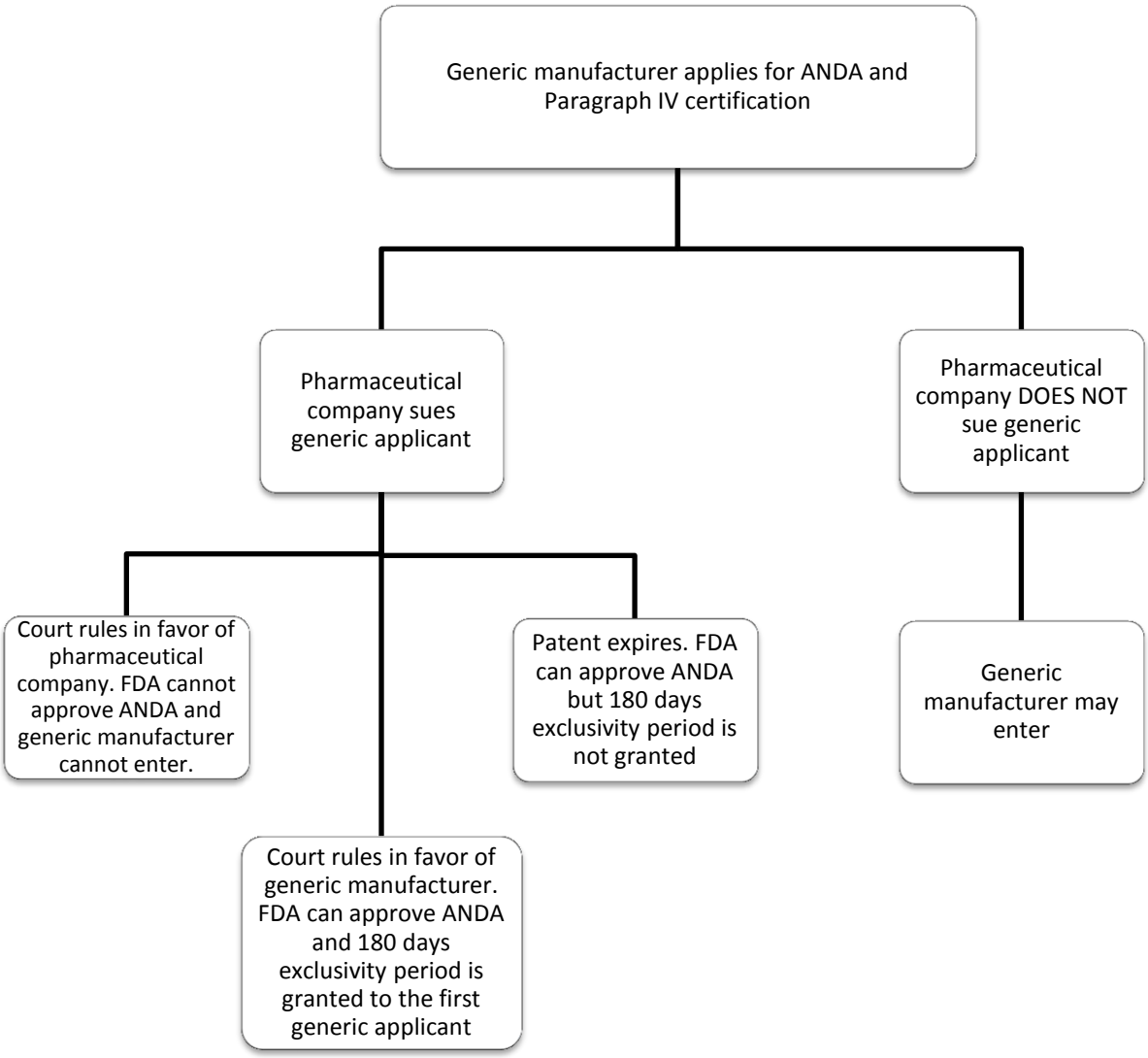
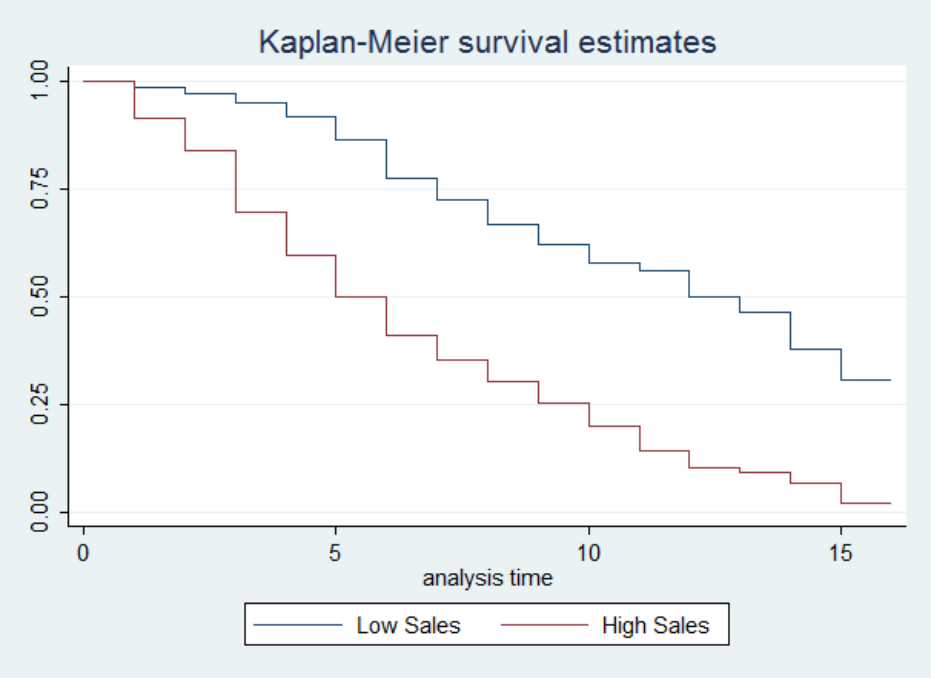
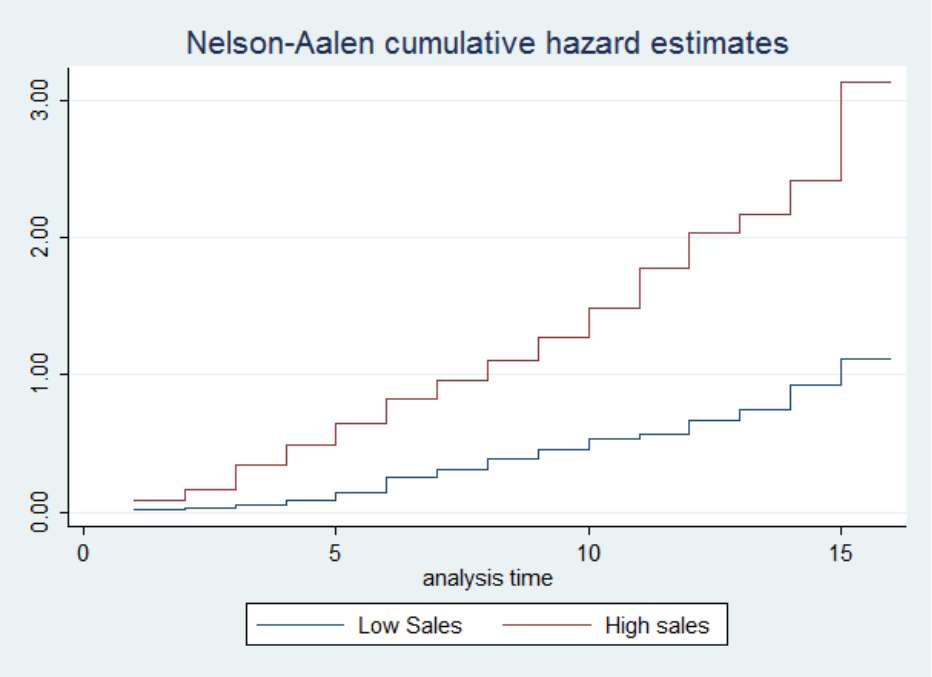


Figure 4.1 Paragraph IV challenge description
Source: Re-adapted from Bulow (2004)



(a) Survival Function by sales



(b) Hazard Function by sales

Figure 4.3 Survival function (a) and Hazard function (b) by sales

CHAPTER 5

CONCLUSION

In this dissertation, I have attempted to highlight the central role of licensed technologies as drivers of firm-level innovative outcomes. However, in contrast to extensive existing research that focuses on the importance of markets for technology and the antecedents of licensing, I examine the significance of in-licensing investments. It is crucial to understand when acquired technologies generate synergies with existing capabilities, as they are more reliable than patents developed internally. I rely on the markets for technology framework as the primary conceptual lens to analyze drivers of complementarity and the knowledge assimilation process. I also use litigation literature to focus on the role of external patents in intellectual property rights lawsuits. As a result, the main contribution of this dissertation is to highlight the impact of in-licensing on different firm-level performance variables: the ability of an organization to generate synergies between types of R&D investments, the capacity of an organization to assimilate and adopt new knowledge when the existing knowledge stock is high, and the capability of an organization to effectively select and use external patents in "Paragraph IV challenges."

In more details, in the first chapter I show that on average the relationship between in-licensing and internal R&D is neither that of a substitute nor a complement but that the level of complementarity differs between different levels of scientific publications and absorptive capacity, thus suggesting that firms with high levels of publications and large R&D stock are better able to integrate external technologies. In

addition, companies may be able to use knowledge across therapeutic areas additively and therefore experience better levels of complementarity. Finally, complementarity increase for firms with a larger stock of prior licensing experience. In other words, experience in licensing agreements may facilitate the management and integration of the acquired technologies.

In the second chapter, results suggest thath reliance on internal knowledge negatively moderates the impact of licensing on firm performance. It may be possible that internal knowledge accumulation favors the development of an inward oriented process and, as a consequence, firms may suffer from the Not Invented Here syndrome and have negative biases towards external knowledge. This negative effect is moderated through two mechanisms: high level of absorptive capacity and decentralized organizational structure. The results have important managerial implications. This bias towards external technologies may limit the adoption of open innovation strategies and the exploitation of external technologies. As a consequence, firms need to create fuzzier organizational boundaries to incentivize both internal knowledge accumulation and external knowledge adoption.

In the third chapter, I find that external technologies are more reliable than internally developed patents. The hazard of a Paragraph IV challenge is independent of the types of patents linked to the drug but it mainly depends on the level of sales, which is directly related to market profitability. However, external patents increase the probability that a branded firm wins the litigation suit; therefore, they prevent generic manufacturers from entering the market. There are two explanations for this result: first, pharmaceutical companies can effectively select the best external patents and second, the

role of cospecialized assets favors the incumbent that may win against new entrants by contracting the focal technology.

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